METHODS AND APPARATUSES FOR STABILIZING THE SPINE THROUGH AN ACCESS DEVICE

Background of the Invention

Field of the Invention

[0001] This application relates generally to methods and apparatuses for performing minimally invasive surgery, and more particularly to methods and apparatuses for performing procedures for stabilizing adjacent bones while preserving motion therebetween.

Description of the Related Art

[0002] In the past, patients suffering from degenerative spine conditions, such as progressive degeneration of intervertebral discs, have been treated by various techniques. For example, fixation and fusion are two procedures that are sometimes performed in combination to address degeneration of the intervertebral discs. Fusion involves the replacement of an intervertebral disc with a bone graft intended to fuse the adjacent vertebrae together. Fixation provide an external structure that bridges from one vertebra to an adjacent vertebra to eliminate motion therebetween. While fusion and fixation may reduce some symptoms of disc degeneration, the elimination of motion reduces the patient's flexibility and may cause other complications.

[0003] Also, these procedures are typically performed by way of open spine surgery. In open spine surgery, the surgeon typically make large incisions and cuts or strips muscle tissue surrounding the spine to provide open access to the troubled area. This technique exposes nerves in the open area, which can be injured when exposed. Consequently, open surgery carries significant risks of scarring, pain, nerve damage, and blood loss. Open surgery also subjects patients to extended recovery times.

[0004] Less invasive techniques have been proposed to reduce the trauma of open spine surgery. For example, a constant diameter cannula has been proposed to reduce incision length associated with open surgery. Unfortunately, such cannulae are usually very narrow and therefore they provides minimal space for the physician to observe the body structures and manipulate surgical instruments.

Summary of the Invention

[0005] Accordingly there is a need in the art for minimally invasive systems and methods for stabilizing adjacent bone, e.g., vertebrae, while preserving motion therebetween. These systems and methods may advantageously provide a more normal post-recovery range of motion, and may also limit stresses associated with other stabilization procedures placed on adjacent vertebrae and intervening discs.

[0006] In one embodiment, at least two adjacent vertebrae of the spine a patient are stabilized. An access device is inserted through an incision in the skin of the patient generally posteriorly. The access device is advanced until a distal portion thereof is located adjacent the spine. The access device is inserted in a first configuration that has a first cross-sectional area at the distal portion thereof. The access device is configured such that the distal portion thereof is enlarged from the first configuration to a second configuration wherein the distal portion is large enough to extend across at least a portion of the adjacent vertebrae. A bone probe is advanced through the access device to one of the two adjacent vertebrae. A hole is formed in one of the two adjacent vertebrae. A tap is advanced through the access device to one of the two adjacent vertebrae. The tap is advanced into at least a portion of the hole to create a tapped hole portion. A fastener is delivered through the access device to the hole. A connecting element that is delivered through the access device. The dynamic connecting element is coupled to the fastener in a manner that permits motion between the adjacent vertebrae.

[0007] In another embodiment, two adjacent vertebrae in a spine of a patient are treated. An access device is inserted through a minimally invasive incision in the skin of the patient. The access device is advanced until a distal portion thereof is located adjacent the spine. The access device is expanded from a first configuration to a second configuration. The second configuration has an enlarged cross-sectional area at the distal portion thereof such that the distal portion extends across at least a portion of the two adjacent vertebrae. A motion preserving, stabilization device is delivered to a location between the two adjacent vertebrae through the access device.

[0008] In another embodiment, a method of treating a spine of a patient is provided. An access device is inserted through a minimally invasive incision in the skin of

the patient. The access device is advanced until a distal portion thereof is located adjacent the spine. The access device is expanded from a first configuration to a second configuration. The second configuration has an enlarged cross-sectional area at the distal portion thereof such that the distal portion extends across at least one of two adjacent vertebrae. A stabilization device is delivered through the access device to a location between the two adjacent vertebrae. The stabilization device is configured to preserve motion between the two adjacent vertebrae.

[0009] In another embodiment, a system is provided that is configured to apply a dynamic stabilization device between two adjacent vertebrae. The system includes an access device, a bone probe, and a tap. The access device has a first configuration and a second configuration. The first configuration has a first cross-sectional area at the distal portion thereof for insertion. In the second configuration, the distal portion is enlarged to extend across at least one of the two adjacent vertebrae. The access device is configured to permit the dynamic stabilization device to be advanced therethrough. The bone probe is configured to be advanced through the access device to form a hole in one of the two adjacent vertebrae. The tap is configured to be advanced through the access device to thread the hole to create a tapped hole.

Brief Description of the Drawings

[0010] Further objects, features and advantages of the invention will become apparent from the following detailed description taken in conjunction with the accompanying figures showing illustrative embodiments of the invention, in which:

[0011] **FIGURE 1** is a perspective view of one embodiment of a surgical system and one embodiment of a method for treating the spine of a patient;

[0012] **FIGURE 2** is a perspective view of one embodiment of an expandable conduit in a reduced profile configuration;

[0013] **FIGURE 3** is a perspective view of the expandable conduit of **FIGURE 2** in a first enlarged configuration;

[0014] **FIGURE 4** is a perspective view of the expandable conduit of **FIGURE 2** in a second enlarged configuration;

[0015] **FIGURE 5** is a view of one embodiment of a skirt portion of an expandable conduit;

[0016] **FIGURE 6** is a view of another embodiment of a skirt portion of an expandable conduit;

[0017] **FIGURE 7** is a perspective view of another embodiment of an expandable conduit in an enlarged configuration;

[0018] **FIGURE 8** is an enlarged sectional view of the expandable conduit of **FIGURE 7** taken along lines 8-8 of **FIGURE 7**;

[0019] **FIGURE 9** is a sectional view of the expandable conduit of **FIGURE 7** taken along lines 9-9 of **FIGURE 7**;

[0020] **FIGURE 10** is a perspective view of another embodiment of an expandable conduit in an enlarged configuration;

[0021] **FIGURE 11** is an enlarged sectional view of the expandable conduit of **FIGURE 10** taken along lines 11-11 of **FIGURE 10**;

[0022] **FIGURE 12** is a sectional view of the expandable conduit of **FIGURE 10** taken along lines 12-12 of **FIGURE 10**;

[0023] **FIGURE 13** is a view of a portion of another embodiment of the expandable conduit;

[0024] **FIGURE 14** is a view of a portion of another embodiment of the expandable conduit;

[0025] **FIGURE 15** is a sectional view illustrating one embodiment of a stage of one embodiment of a method for treating the spine of a patient;

[0026] **FIGURE 16** is a side view of one embodiment of an expander apparatus in a reduced profile configuration;

[0027] **FIGURE 17** is a side view of the expander apparatus of **FIGURE 16** in an expanded configuration;

[0028] **FIGURE 18** is a sectional view of the expander apparatus of **FIGURES 16-17** inserted into the expandable conduit of **FIGURE 2**, which has been inserted into a patient;

[0029] **FIGURE 19** is a sectional view of the expander apparatus of **FIGURES 16-17** inserted into the expandable conduit of **FIGURE 2** and expanded to the expanded configuration to retract tissue;

[0030] **FIGURE 20** is an exploded perspective view of one embodiment of an endoscope mount platform;

[0031] **FIGURE 21** is a top view of the endoscope mount platform of **FIGURE 20** coupled with one embodiment of an indexing arm and one embodiment of an endoscope;

[0032] **FIGURE 22** is a side view of the endoscope mount platform of **FIGURE 20** illustrated with one embodiment of an indexing arm and one embodiment of an endoscope;

[0033] **FIGURE 23** is a perspective view of one embodiment of an indexing collar of the endoscope mount platform **FIGURE 20**;

[0034] **FIGURE 24** is a perspective view of one embodiment of an endoscope;

[0035] **FIGURE 25** is a partial sectional view of one embodiment of a stage of one embodiment of a method for treating the spine of a patient;

[0036] **FIGURE 26** is a perspective view of one embodiment of a fastener;

[0037] **FIGURE 27** is an exploded perspective view of the fastener of **FIGURE 26**;

[0038] **FIGURE 27(a)** is an enlarged side view of one embodiment of a biasing member illustrated in **FIGURE 27** taken from the perspective of the arrow 27a;

[0039] **FIGURE 28** is a perspective view of one embodiment of a surgical instrument;

[0040] **FIGURE 29** is an enlarged sectional view of the fastener of **FIGURES 26-27** coupled with the surgical instrument of **FIGURE 28**, illustrating one embodiment of a stage of one embodiment of a method for treating the spine of a patient;

[0041] **FIGURE 30** is side view of one embodiment of another surgical instrument;

[0042] **FIGURE 31** is a partial sectional view of one embodiment of a stage of one embodiment of a method for treating the spine of a patient;

[0043] **FIGURE 32** is a side view of one embodiment of another surgical instrument;

[0044] **FIGURE 33** is a perspective view similar to **FIGURE 31** illustrating the apparatuses of **FIGURES 26** and **32**, in one embodiment of a stage of one embodiment of a method for treating the spine of a patient;

[0045] **FIGURE 34** is an enlarged sectional view of the apparatus of **FIGURES 26** and **32**, illustrating one embodiment of a stage of one embodiment of a method for treating the spine of a patient;

[0046] **FIGURE 35** is an enlarged sectional similar to **FIGURE 34**, illustrating one embodiment of a stage of one embodiment of a method for treating the spine of a patient;

[0047] **FIGURE 36** is an enlarged view in partial section illustrating one embodiment of a stage of one embodiment of a method for treating the spine of a patient;

[0048] **FIGURE 37** is a partial view illustrating one embodiment of a stage of one embodiment of a method for treating the spine of a patient;

[0049] **FIGURE 38** is a schematic view of one embodiment of a dynamic stabilization device shown applied to a spine of a patient;

[0050] **FIGURE 39** is a partial cross-sectional view of a portion of the dynamic stabilization device of **FIGURE 38**;

[0051] **FIGURE 40** is a detail view of a portion of the dynamic stabilization device of **FIGURE 38**;

[0052] **FIGURE 41** is an elevation view illustrating one embodiment of a dynamic stabilization device applied to a human spine;

[0053] **FIGURE 42** is a lateral elevation view illustrating one embodiment of a dynamic stabilization device applied to a human spine;

[0054] **FIGURE 43** is a detail view illustrating one embodiment of a dynamic stabilization device;

[0055] **FIGURE 44** is a perspective view illustrating one embodiment of a dynamic stabilization device applied to a human spine;

[0056] **FIGURE 45** is an elevation view illustrating one embodiment of a dynamic stabilization device applied to a human spine;

[0057] **FIGURE 46** is a schematic view of one embodiment of an access device applied through the skin of a patient to provide access to a surgical location near the spine in connection with a dynamic stabilization procedure;

[0058] **FIGURE 47** is a lateral view of two adjacent vertebrae of the spine to which the access device of **FIGURE 46** has been applied, illustrating the application of one embodiment of a dynamic stabilizer;

[0059] **FIGURE 48** is a lateral view of two adjacent vertebrae of the spine to which the access device of **FIGURE 46** has been applied, illustrating the application of another embodiment of a dynamic stabilizer; and

[0060] **FIGURE 49** is a lateral view of two adjacent vertebrae of the spine to which the access device of **FIGURE 46** has been applied, illustrating the application of another embodiment of a dynamic stabilizer.

[0061] Throughout the figures, the same reference numerals and characters, unless otherwise stated, are used to denote like features, elements, components or portions of the illustrated embodiments. Moreover, while the subject invention will now be described in detail with reference to the figures, it is done so in connection with the illustrative embodiments. It is intended that changes and modifications can be made to the described embodiments without departing from the true scope and spirit of the subject invention as defined by the appended claims.

Detailed Description of the Preferred Embodiments

[0062] As should be understood in view of the following detailed description, this application is directed to apparatuses and methods for treating the spine of a patient through an access device, also referred to herein as an expandable conduit. More particularly, the systems described below provide access to surgical locations at or near the spine and provide a variety of tools useful in performing treatment of the spine. Also, the systems described herein enable a surgeon to perform a wide variety of methods as described herein.

I. SYSTEMS FOR PERFORMING PROCEDURES AT A SURGICAL LOCATION

[0063] Various embodiments of apparatuses and procedures described herein will be discussed in terms minimally invasive procedures and apparatuses, e.g., of endoscopic apparatuses and procedures. However, many aspects of the present invention may find use in conventional, open, and mini-open procedures. In the drawings and description which

follows, the term "proximal," as is traditional, refers to the end portion of the apparatus which is closest to the operator, while the term "distal" will refer to the end portion which is farthest from the operator.

[0064] **FIGURE 1** shows one embodiment of a surgical system 10 that can be used to perform a variety of methods or procedures. In at least a portion of the procedure, as discussed more fully below, the patient P typically is placed in the prone position on operating table T, taking care that the abdomen is not compressed and physiological lordosis is preserved, as is known in the art. The physician D is able to access the surgical site and perform the surgical procedure with the components of the system 10, which will be described in greater detail herein. The system 10 may be supported, in part, by a mechanical support arm A, such as the type generally disclosed in U.S. Patent No. 4,863,133, which is hereby incorporated by reference herein in its entirety. One mechanical arm of this type is manufactured by Leonard Medical, Inc., 1464 Holcomb Road, Huntington Valley, PA, 19006.

[0065] Visualization of the surgical site may be achieved in any suitable manner, e.g., by use of a viewing element, such as an endoscope, a camera, loupes, a microscope, direct visualization, or any other suitable viewing element, or a combination of the foregoing. In one embodiment, the viewing element provides a video signal representing images, such as images of the surgical site, to a monitor M. The viewing element may be an endoscope and camera which captures images to be displayed on the monitor M whereby the physician D is able to view the surgical site as the procedure is being performed. The endoscope and camera will be described in greater detail herein.

[0066] The systems and procedures will be described herein in connection with minimally invasive postero-lateral spinal surgery. One such method is a two level postero-lateral fixation of the spine involving the L4, L5, and S1 vertebrae. (In the drawings, the vertebrae will generally be denoted by reference letter V.) The usefulness of the apparatuses and procedures is neither restricted to the postero-lateral approach nor to the L4, L5, and S1 vertebrae, but it may be used in other anatomical approaches and other vertebra(e) within the cervical, thoracic, and lumbar regions of the spine. The procedures may be directed toward surgery involving one or more vertebral levels. It is also useful for anterior and lateral

procedures. Moreover, it is believed that the invention is also particularly useful where any body structures must be accessed beneath the skin and muscle tissue of the patient, and where it desirable to provide sufficient space and visibility in order to manipulate surgical instruments and treat the underlying body structures. For example, certain features or instrumentation described herein are particularly useful for a minimally invasive procedures, e.g., arthroscopic procedures. As discussed more fully below, one embodiment of an apparatus described herein provides an expandable conduit that has an expandable distal portion. The expandable distal portion prevents or substantially prevents the expandable conduit or instruments extended therethrough to the surgical site from being dislodging or popping out of the operative site.

[0067] The system 10 includes an expandable conduit or access device that provides a internal passage for surgical instruments to be inserted through the skin and muscle tissue of the patient P to the surgical site. The expandable conduit has a wall portion defining reduced profile configuration for initial percutaneous insertion into the patient. This wall portion may have any suitable arrangement. In one embodiment, discussed in more detail below, the wall portion has a generally tubular configuration that may be passed over a dilator that has been inserted into the patient to atraumatically enlarge an opening sufficiently large to receive the expandable conduit therein.

[0068] The wall portion of the expandable conduit is subsequently expanded to an enlarged configuration, by moving against the surrounding muscle tissue to at least partially define an enlarged surgical space in which the surgical procedures will be performed. In a sense, it acts as its own dilator. The expandable conduit may also be thought of as a retractor, and may be referred to herein as such. Typically, but not by way of limitation, the distal portion expands to a greater extent than the proximal portion, because the surgical procedures are to be performed at the surgical site which is adjacent the distal portion when the expandable conduit is inserted into the patient.

[0069] While in the reduced profile configuration, the expandable conduit defines a first unexpanded configuration. Thereafter, the expandable conduit enlarges the surgical space defined thereby by engaging the tissue surrounding the conduit and displacing the tissue radially outwardly as the conduit expands. The expandable conduit may be sufficiently

rigid to displace such tissue during the expansion thereof. The expandable conduit may be resiliently biased to expand from the reduced profile configuration to the enlarged configuration. In addition, the conduit may also be manually expanded by an expander device with or without one or more surgical instruments inserted therein, as will be described below. The surgical site is at least partially defined by the expanded conduit itself. During expansion, the conduit moves from the first overlapping configuration to a second overlapping configuration.

[0070] In addition to enlargement, the distal end portion of the expandable conduit may be configured for relative movement with respect to the proximal end portion in order to allow the physician to precisely position the distal end portion at the desired location. This relative movement also provides the advantage that the proximal portion of the expandable conduit nearest the physician D may remain substantially stable during such distal movement. In an exemplary embodiment, the distal portion is a separate component which is pivotably or movably attached relative to the proximal portion. In another embodiment, the distal portion is flexible or resilient in order to permit such relative movement.

[0071] One embodiment of an expandable conduit is illustrated in **FIGURES 2-6** and designated by reference number 20. The expandable conduit 20 includes a proximal wall portion 22, which has a tubular configuration, and a distal wall portion, which is an expandable skirt portion 24. The skirt portion 24 is enlargeable from a reduced profile configuration having an initial dimension 26 and corresponding cross-sectional area (illustrated in **FIGURE 2**), to an enlarged configuration having a dimension 28 and corresponding cross-sectional area (illustrated in **FIGURE 4**). In one embodiment, the skirt portion 24 is attached to the proximal wall portion 22 with a rivet 30, pin, or similar connecting device to permit movement of the skirt portion 24 relative to the proximal wall portion 22.

[0072] In the illustrated embodiment, the skirt portion 24 is manufactured from a resilient material, such as stainless steel. The skirt portion 24 is manufactured so that it normally assumes an expanded configuration illustrated in **FIGURE 4**. As illustrated in **FIGURE 3**, the skirt portion 24 may assume an intermediate dimension 34 and

corresponding cross-sectional area, which is greater than the dimension 26 of the reduced profile configuration of **FIGURE 2**, and smaller than the dimension 28 of the enlarged configuration of **FIGURE 4**. The skirt portion 24 may assume the intermediate configuration of **FIGURE 3** when deployed in the patient in response to the force of the tissue acting on the skirt portion 24. The intermediate dimension 34 will depend upon several factors, including the rigidity of the skirt portion 24, the surrounding tissue, and whether such surrounding tissue has relaxed or tightened during the course of the procedure. An outer plastic sleeve 32 (illustrated in dashed line in **FIGURE 2**) may be provided which surrounds the expandable conduit 20 and maintains the skirt portion 24 in the reduced profile configuration. The outer sleeve 32 may have a braided polyester suture embedded within it (not shown), aligned substantially along the longitudinal axis thereof; such that when the suture is withdrawn, the outer sleeve 32 is torn, which allows the expandable conduit 20 to resiliently expand from the reduced profile configuration of **FIGURE 2** to the expanded configurations of **FIGURES 3-4**. While in the reduced profile configuration of **FIGURE 2**, the skirt portion 24 defines a first overlapping configuration 33, as illustrated by the dashed line. As the skirt portion 24 resiliently expands, the skirt portion 24 assumes the expanded configuration, as illustrated in **FIGURES 3-4**.

[0073] The skirt portion 24 is sufficiently rigid that it is capable of displacing the tissue surrounding the skirt portion 24 as it expands. Depending upon the resistance exerted by surrounding tissue, the skirt portion is sufficiently rigid to provide some resistance against the tissue to remain in the configurations of **FIGURES 3-4**. Moreover, the expanded configuration of the skirt portion 24 is at least partially supported by the body tissue of the patient. The rigidity of the skirt portion 24 and the greater expansion at the distal portion creates a stable configuration that is at least temporarily stationary in the patient, which frees the physician from the need to actively support the conduit 20 until an endoscope mount platform 300 and a support arm 400 are subsequently added in one embodiment (see **FIGURES 21-22**).

[0074] The skirt portion 24 of the expandable conduit 20 is illustrated in an initial flattened configuration in **FIGURE 5**. The skirt portion 24 may be manufactured from a sheet of stainless steel having a thickness of about 0.007 inches. In various embodiments, the

dimension 28 of the skirt portion 24 is about equal to or greater than 50 mm, is about equal to or greater than 60 mm, is about equal to or greater than 70 mm, is about equal to or greater than 80 mm, or is any other suitable size, when the skirt portion 24 is in the enlarged configuration. In one embodiment, the dimension 28 is about 63 mm, when the skirt portion 24 is in the enlarged configuration. As discussed above, the unrestricted shape of the skirt portion 24 preferably is a circular or an oblong shape. The skirt portion 24 may also take on an oval shape, wherein the dimension 28 would define a longer dimension the skirt portion 24 and would be about 85 mm in one embodiment. In another embodiment, the skirt portion 24 has an oval shape and the dimension 28 defines a longer dimension of the skirt portion 24 and would be about 63 mm. An increased thickness, e.g., about 0.010 inches, may be used in connection with skirt portions having a larger diameter, such as about 65 mm. Other materials, such as nitinol or plastics having similar properties, may also be useful.

[0075] As discussed above, the skirt portion 24 is attached to the proximal wall portion 22 with a pivotable connection, such as rivet 30. A pair of rivet holes 36 are provided in the skirt portion 24 to receive the rivet 30. The skirt portion 24 also has two free ends 38 and 40 in one embodiment that are secured by a slidable connection, such as second rivet 44 (not shown in **FIGURE 5**, illustrated in **FIGURES 2-4**). A pair of complementary slots 46 and 48 are defined in the skirt portion 24 adjacent the free ends 38 and 40. The rivet 44 is permitted to move freely within the slots 46 and 48. This slot and rivet configuration allows the skirt portion 24 to move between the reduced profile configuration of **FIGURE 2** and the enlarged or expanded configurations of **FIGURES 3-4**. The use of a pair of slots 46 and 48 reduces the risk of the "button-holing" of the rivet 44, e.g., a situation in which the opening of the slot becomes distorted and enlarged such that the rivet may slide out of the slot, and cause failure of the device. However, the likelihood of such occurrence is reduced in skirt portion 24 because each of the slots 46 and 48 in the double slot configuration has a relatively shorter length than a single slot configuration. Being shorter, the slots 46, 48 are less likely to be distorted to the extent that a rivet may slide out of position. In addition, the configuration of rivet 44 and slots 46 and 48 permits a smoother operation of enlarging and reducing the skirt portion 24, and allows the skirt portion 24 to expand to span as many as three vertebrae, e.g.,

L4, L5, and S1, to perform multi-level fixation alone or in combination with a variety of other procedures, as discussed below.

[0076] An additional feature of the skirt portion 24 is the provision of a shallow concave profile 50 defined along the distal edge of the skirt portion 24, which allows for improved placement of the skirt portion 24 with respect to the body structures and the surgical instruments defined herein. In one embodiment, a pair of small scalloped or notched portions 56 and 58, are provided, as illustrated in **FIGURE 5**. When the skirt portion 24 is assembled, the notched portions 56 and 58 are oriented in the cephcaudal direction (indicated by an arrow 60 in **FIGURE 4)** and permit instrumentation, such as an elongated member 650 used in a fixation procedure (described in detail below), to extend beyond the area enclosed by the skirt portion 24 without moving or raising the skirt portion 24 from its location to allow the elongated member 650 to pass under the skirt portion 24. The notched portions 56, 58 are optional, as illustrated in connection with another embodiment of an expandable conduit 54, illustrated in **FIGURE 6**, and may be eliminated where the physician deems the notches to be unnecessary for the procedures to be performed (e.g., where fixation does not require extended access, as discussed more fully below.)

[0077] As illustrated in **FIGURE 4**, the skirt portion 24 may be expanded to a substantially conical configuration having a substantially circular or elliptical profile. In another embodiment, features may be provided on the skirt portion which facilitate the bending of the skirt portion at several locations to provide a pre-formed enlarged configuration. For example, another embodiment of an expandable conduit 70, illustrated in **FIGURES 7- 9**, provides a skirt portion 74 that has four sections 76a, 76b, 76c, 76d having a reduced thickness. For a skirt portion 74 having a thickness 78 of about .007 inches, reduced thickness sections 76a, 76b, 76c, 76d may have a thickness 80 of about 0.002-0.004 inches (**FIGURE 8**). The reduced thickness sections 76a, 76b, 76c, 76d may have a width 82 of about 1-5 mm. The thickness 78 of the skirt portion 74 may be reduced by milling or grinding, as is known in the art. When the skirt portion 74 is opened, it moves toward a substantially rectangular configuration, as shown in **FIGURE 9**, subject to the resisting forces of the body tissue. In another embodiment (not shown), a skirt portion may be

provided with two reduced thickness sections (rather than the four reduced thickness sections of skirt 74) which would produce a substantially "football"-shaped access area.

[0078] **FIGURES 10-12** show another embodiment of an expandable conduit 80. The expandable conduit 80 has a skirt portion 84 with a plurality of perforations 86. The perforations 86 advantageously increase the flexibility at selected locations. The size and number of perforations 86 may vary depending upon the desired flexibility and durability. In another embodiment, the skirt portion 84 may be scored or otherwise provided with a groove or rib in order to facilitate the bending of the skirt portion at the desired location.

[0079] **FIGURE 13** illustrates another embodiment of an expandable conduit that has a skirt portion 94 having one slot 96 and an aperture 98. A rivet (not shown) is stationary with respect to the aperture 98 and slides within the slot 96. **FIGURE 14** illustrates another embodiment of an expandable conduit that has a skirt portion 104 that includes an aperture 108. The apertures 108 receives a rivet (not shown) that slides within elongated slot 106.

[0080] Further details of the expandable conduit are described in U.S. Patent 6,187,00, and in U.S. Patent Application No. 09/772,605, filed January 30, 2001, U.S. Application 10/361,887 filed February 10, 2003, and Application No. 10/280,489 filed October 25, 2002, which are incorporated by reference in their entirety herein.

[0081] In one embodiment of a procedure, an early stage involves determining a point in the skin of the patient at which to insert the expandable conduit. The access point preferably corresponds to the posterior-lateral aspects of the spine. Manual palpation and Anterior-Posterior (AP) fluoroscopy may be used to determine preferred or optimal locations for forming an incision in the skin of the patient. In one embodiment, the expandable conduit 20 preferably is placed midway (in the cephcaudal direction) between the L4 through S1 vertebrae, centrally about 4-7 cm from the midline of the spine.

[0082] After the above-described location is determined, an incision is made at the location. A guide wire (not shown) is introduced under fluoroscopic guidance through the skin, fascia, and muscle to the approximate surgical site. A series of dilators is used to sequentially expand the incision to the desired width, about 23 mm in one procedure, without damaging the structure of surrounding tissue and muscles. A first dilator is placed over the guide wire, which expands the opening. The guide wire is then subsequently removed. A

second dilator that is slightly larger than the first dilator is placed over the first dilator, which expands the opening further. Once the second dilator is in place, the first dilator is subsequently removed. This process of (1) introducing a next-larger-sized dilator coaxially over the previous dilator and (2) subsequently removing the previous dilator when the next-larger-sized dilator is in place continues until an opening of the desired size is created in the skin, muscle, and subcutaneous tissue. In one embodiment of the method, desired opening size is about 23 mm. (Other dimensions of the opening, e.g., about 20 mm, 27 mm, 30 mm, etc., are also useful with this apparatus in connection with spinal surgery, and still other dimensions are contemplated.)

[0083] **FIGURE 15** shows that following placement of a dilator 120, which is the largest dilator in the above-described dilation process, the expandable conduit 20 is introduced in its reduced profile configuration and positioned in a surrounding relationship over the dilator 120. The dilator 120 is subsequently removed from the patient, and the expandable conduit 20 is allowed to remain in position.

[0084] Once positioned in the patient, the expandable conduit 20 may be enlarged to provide a passage for the insertion of various surgical instruments and to provide an enlarged space for performing the procedures described herein. As described above, the expandable conduit may achieve the enlargement in several ways. In one embodiment, a distal portion of the conduit may be enlarged, and a proximal portion may maintain a constant diameter. The relative lengths of the proximal portion 22 and the skirt portion 24 may be adjusted to vary the overall expansion of the conduit 20. Alternatively, such expansion may extend along the entire length of the expandable conduit 20. In one embodiment of a procedure, the expandable conduit 20 may be expanded by removing a suture 35 and tearing the outer sleeve 32 surrounding the expandable conduit 20, and subsequently allowing the skirt portion 24 to resiliently expand towards its fully expanded configuration as (illustrated in **FIGURE 4**) to create an enlarged surgical space from the L4 to the S1 vertebrae. The resisting force exerted on the skirt portion 24 may result in the skirt portion 24 assuming the intermediate configuration illustrated in **FIGURE 3**. Under many circumstances, the space created by the skirt portion 24 in the intermediate configuration is a sufficiently large working space to perform the procedure described herein. Once the skirt

portion 24 has expanded, the rigidity and resilient characteristics of the skirt portion 24 allow the expandable conduit 20 to resist closing to the reduced profile configuration of **FIGURE 2** and to at least temporarily resist being expelled from the incision. These characteristics create a stable configuration for the conduit 20 to remain in position in the body, supported by the surrounding tissue. It is understood that additional support may be needed, especially if an endoscope is added.

[0085] According to one embodiment of a procedures, the expandable conduit 20 may be further enlarged at the skirt portion 24 using an expander apparatus to create a surgical access space. An expander apparatus useful for enlarging the expandable conduit has a reduced profile configuration and an enlarged configuration. The expander apparatus is inserted into the expandable conduit in the reduced profile configuration, and subsequently expanded to the enlarged configuration. The expansion of the expander apparatus also causes the expandable conduit to be expanded to the enlarged configuration. In some embodiments, the expander apparatus may increase the diameter of the expandable conduit along substantially its entire length in a conical configuration. In other embodiments, the expander apparatus expands only a distal portion of the expandable conduit, allowing a proximal portion to maintain a constant diameter.

[0086] In addition to expanding the expandable conduit, the expander apparatus may also be used to position the distal portion of the expandable conduit at the desired location for the surgical procedure. The expander engages an interior wall of the expandable conduit, and moves the conduit to the proper location. For the embodiments in which the distal portion of the expandable conduit is relatively movable with respect to the proximal portion, the expander apparatus is useful to position the distal portion without substantially disturbing the proximal portion.

[0087] In some procedures, an expander apparatus is used to further expand the skirt portion 24 towards the enlarged configuration (illustrated in **FIGURE 4**). The expander apparatus is inserted into the expandable conduit, and typically has two or more members which are movable to engage the interior wall of the skirt portion 24 and apply a force sufficient to further expand the skirt portion 24. **FIGURES 16** and **17** show one embodiment of an expander apparatus 200 that has a first component 202 and a second component 204. A

first component 202 and a second component 204 of the expander apparatus 200 are arranged in a tongs-like configuration and are pivotable about a pin 206. The first and second components 202 and 204 are typically constructed of steel having a thickness of about 9.7 mm. Each of the first and second components 202 and 204 has a proximal handle portion 208 and a distal expander portion 210. Each proximal handle portion 208 has a finger grip 212 that may extend transversely from an axis, e.g., a longitudinal axis 214, of the apparatus 200. The proximal handle portion 208 may further include a stop element, such as flange 216, that extends transversely from the longitudinal axis 214. The flange 216 is dimensioned to engage the proximal end 25 of the expandable conduit 20 when the apparatus 200 is inserted a predetermined depth. This arrangement provides a visual and tactile indication of the proper depth for inserting the expander apparatus 200. In one embodiment, a dimension 218 from the flange 216 to the distal tip 220 is about 106 mm. The dimension 218 is determined by the typical depth of the body structures beneath the skin surface at which the surgical procedure is being performed. The distal portions 210 are each provided with an outer surface 222 for engaging the inside wall of the skirt portion 24. The outer surface 222 is a frusto-conical surface in one embodiment. The expander apparatus 200 has an unexpanded distal width 224 at the distal tip 220 that is about 18.5 mm in one embodiment.

[0088] In use, the finger grips 212 are approximated towards one another, as indicated by an arrow A in **FIGURE 17**, which causes the distal portions 210 to move to the enlarged configuration, as indicated by arrows B. The components 202 and 204 are also provided with a cooperating tab 226 and shoulder portion 228 which are configured for mutual engagement when the distal portions 210 are in the expanded configuration. In the illustrated embodiment, the expander apparatus 200 has an expanded distal width 230 that extends between the distal portions 210. The expanded distal width 230 can be about 65 mm or less, about as large as 83 mm or less, or any other suitable width. The tab 226 and shoulder portion 228 together limit the expansion of the expander apparatus 200 to prevent expansion of the skirt portion 24 of the expandable conduit 20 beyond its designed dimension, and to minimize trauma to the underlying tissue. Further details of the expander apparatus are described in US Patent Application No. 09/906,463 filed July 16, 2001, which is incorporated by reference in their entirety herein.

[0089] When the expandable conduit 20 is inserted into the patient and the outer sleeve 32 is removed, the skirt portion 24 expands to a point where the outward resilient expansion of the skirt portion 24 is balanced by the force of the surrounding tissue. The surgical space defined by the conduit may be sufficient to perform any of a number of surgical procedures or combination of surgical procedures described herein. However, if it is desired to expand the expandable conduit 20 further, the expander apparatus 200 may be inserted into the expandable conduit 20 in the reduced profile configuration until the shoulder portions 216 are in approximation with the proximal end 25 of the skirt portion 24 of the expandable conduit 20, as shown in **FIGURE 18**.

[0090] **FIGURE 18** shows the expander apparatus 200 is inserted in the expandable conduit 20 in the reduced profiled configuration. Expansion of the expander apparatus 200 is achieved by approximating the handle portions 212 (not shown in **FIGURE 18**), which causes the distal portions 210 of the expander apparatus 200 to move to a spaced apart configuration. As the distal portions 210 move apart and contact the inner wall of the skirt portion 24, the skirt portion 24 is expanded by allowing the rivet 44 to slide within the slots 46 and 48 of the skirt portion 24. When the distal portions 210 reach the maximum expansion of the skirt portion 24 (illustrated by a dashed line in **FIGURE 19**), the tab 226 and shoulder portion 228 of the expander apparatus 200 come into engagement to prevent further expansion of the tong portions (as illustrated in **FIGURE 17**). The conduit 20 may be alternatively further expanded with a balloon or similar device.

[0091] A subsequent, optional step in the procedure is to adjust the location of the distal portion of the expandable conduit 20 relative to the body structures to be operated on. For example, the expander apparatus 200 may also be used to engage the inner wall of the skirt portion 24 of the expandable conduit 20 in order to move the skirt portion 24 of the expandable conduit 20 to the desired location. For an embodiment in which the skirt portion 24 of the expandable conduit 20 is relatively movable relative to the proximal portion, e.g. by use of the rivet 30, the expander apparatus 200 is useful to position the skirt portion 24 without substantially disturbing the proximal portion 22 or the tissues closer to the skin surface of the patient. As will be described below, the ability to move the distal end portion, e.g., the skirt portion 24, without disturbing the proximal portion is especially beneficial

when an additional apparatus is mounted relative to the proximal portion of the expandable conduit, as described below.

[0092] An endoscope mount platform 300 and indexing arm 400 provide securement of an endoscope 500 on the proximal end 25 of the expandable conduit 20 for remotely viewing the surgical procedure, as illustrated in **FIGURES 20-23**. The endoscope mount platform 300 may also provide several other functions during the surgical procedure. The endoscope mount platform 300 includes a base 302 that extends laterally from a central opening 304 in a general ring-shaped configuration. The base 302 provides an aid for the physician, who is primarily viewing the procedure by observing a monitor, when inserting surgical instruments into the central opening 304. For example, the size of the base 302 provides visual assistance (as it may be observable in the physician's peripheral vision) as well as provides tactile feedback as the instruments are lowered towards the central opening 304 and into the expandable conduit 20.

[0093] The endoscope mount platform 300 further provides a guide portion 306 that extends substantially parallel to a longitudinal axis 308 away from the central opening 304. The base 302 is typically molded as one piece with the guide portion 306. The base 302 and guide portion 306 may be constructed as a suitable polymer such as polyetheretherketone (PEEK).

[0094] The guide portion 306 includes a first upright member 310 that extends upward from the base 302 and a second upright member 312 that extends upward from the base 302. The upright members 310, 312 each have a respective vertical grooves 314 and 315 that can slidably receive an endoscopic mount assembly 318.

[0095] The endoscope 500 (not shown in **FIGURE 20**) is movably mounted to the endoscope mount platform 300 by the endoscope mount assembly 318. The endoscope mount assembly 318 includes an endoscope mount 320 and a saddle unit 322. The saddle unit 322 is slidably mounted is within the grooves 314 and 315 in the upright members 310 and 312. The endoscope mount 320 receives the endoscope 500 through a bore 326 which passes through the endoscope mount 320. Part of the endoscope 500 may extend through the expandable conduit 20 substantially parallel to longitudinal axis 308 into the patient's body 130.

[0096] The endoscope mount 320 is removably positioned in a recess 328 defined in the substantially "U"-shaped saddle unit 322, which is selectively movable in a direction parallel to the longitudinal axis 308 in order to position the endoscope 500 at the desired height within the expandable conduit 20 to provide a zoom feature to physician's view of the surgical procedure.

[0097] A screw mechanism 340 is positioned on the base 302 between the upright members 310 and 312, and is used to selectively move the saddle unit 322, and the endoscope mount 320 and the endoscope 500 which are supported by the saddle unit 322. The screw mechanism 340 comprises a thumb wheel 342 and a spindle 344. The thumb wheel 343 is rotatably mounted in a bore in the base 302. The thumb wheel 342 has an external thread 346 received in a cooperating thread in the base 302. The spindle 344 is mounted for movement substantially parallel to the central axis 308. The spindle 344 has a first end received in a rectangular opening in the saddle unit 322, which inhibits rotational movement of the spindle 344. The second end of the spindle 344 has an external thread which cooperates with an internal thread formed in a bore within the thumb wheel 342. Rotation of the thumb wheel 342 relative to the spindle 344, causes relative axial movement of the spindle unit 344 along with the saddle unit 322. Further details of the endoscope mount platform are described in US Patent Application No. 09/491,808 filed January 28, 2000, Application No. 09/821,297 filed March 29, 2001, and Application 09/940,402 filed August 27, 2001.

[0098] **FIGURE 21**-23 show that the endoscope mount platform 300 is mountable to the support arm 400 in one embodiment. The support arm 400, in turn, preferably is mountable to mechanical support, such as mechanical support arm A, discussed above in connection with **FIGURE 1**. The support arm 400 rests on the proximal end 25 of the expandable conduit 20. The support arm 400 includes an indexing collar 420, which is received in the central opening 304 of the base 302 of endoscope mount platform 300. The indexing collar 420 is substantially toroidal in section and has an outer peripheral wall surface 422, an inner wall surface 424, and a wall thickness 426 that is the distance between the wall surfaces 422, 424. The indexing collar 420 further includes a flange 428, which supports the indexing collar 420 on the support arm 400.

[0099] The collars 420 advantageously make the surgical system 10 a modular in that different expandable conduits 20 may be used with a single endoscope mount platform 300. For example, expandable conduits 20 of different dimensions may be supported by providing of indexing collars 420 to accommodate each conduit size while using a single endoscope mount platform 300. The central opening 304 of the endoscope mount platform 300 has constant dimension, e.g., a diameter of about 32.6 mm. An appropriate indexing collar 420 is selected, e.g., one that is appropriately sized to support a selected expandable conduit 20. Thus the outer wall 422 and the outer diameter 430 are unchanged between different indexing collars 420, although the inner wall 424 and the inner diameter 432 vary to accommodate differently sized conduits 20.

[0100] The indexing collar 420 is mounted to the proximal portion of the expandable conduit 20 and allows angular movement of the endoscope mount platform 300 with respect thereto about the longitudinal axis 308 (as indicated by an arrow C in **FIGURE 21**). The outer wall 422 of the index collar 420 includes a plurality of hemispherical recesses 450 that can receive one or more ball plungers 350 on the endoscope mount platform 300 (indicated in dashed line.) This arrangement permits the endoscope mount platform 300, along with the endoscope 500, to be fixed in a plurality of discrete angular positions. Further details of the support arm and indexing collar are described in US Patent No. 6,361,488, issued March 26, 2002, U.S. Patent No. 6,530,880 issued March 11, 2003, and Application 09/940,402 filed August 27, 2001.

[0101] **FIGURE 24** shows one embodiment of the endoscope 500, which has an elongated configuration that extends into the expandable conduit 20 in order to view the surgical site. In particular, the endoscope 500 has an elongated rod portion 502 and a body portion 504 which is substantially perpendicular thereto. In the illustrated embodiment, the rod portion 502 of endoscope 500 has a diameter of about 4 mm and a length of about 106 mm. Body portion 504 may define a tubular portion 506 which is configured to be slidably received in the bore 326 of endoscope mount 320 as indicated by an arrow D. The slidable mounting of the endoscope 500 on the endoscope mount platform 300 permits the endoscope 500 to adjust to configurations that incorporate different conduit diameters. Additional mobility of the endoscope 500 in viewing the surgical site may be provided by rotating the

endoscope mount platform 300 about the central axis 308 (as indicated by arrow C in **FIGURE 21**).

[0102] The rod portion 502 supports an optical portion (not shown) at a distal end 508 thereof, which may define a field of view of about 105 degrees and a direction of view 511 of about 25-30 degrees. An eyepiece 512 is positioned at an end portion of the body portion 504. A camera (not shown) preferably is attached to the endoscope 500 adjacent the eyepiece 512 with a standard coupler unit. A light post 510 supplies illumination to the surgical site at the distal end portion 508. A preferred camera for use in the system and procedures described herein is a three chip unit that provides greater resolution to the viewed image than a single chip device.

[0103] A subsequent stage in the procedure involves placing the support arm 400 and the endoscope mount platform 300 on the proximal portion, e.g., the proximal end 25, of the expandable conduit 20 (**FIGURES 1** and **22**), and mounting of the endoscope 500 on the endoscope mount platform 300. A next step is insertion of one or more surgical instruments into the expandable conduit 20 to perform the surgical procedure on the body structures at least partially within the operative space defined by the expanded portion of the expandable conduit. **FIGURE 25** shows that in one method, the skirt portion 24 of expandable conduit 20 at least partially defines a surgical site or operative space 90 in which the surgical procedures described herein may be performed. Depending upon the overlap of the skirt portion, the skirt portion may define a surface which is continuous about the circumference or which is discontinuous having one or more gaps where the material of the skirt portion does not overlap.

[0104] One procedure performable through the expandable conduit 20, described in greater detail below, is a two-level spinal fixation. Surgical instruments inserted into the expandable conduit may be used for debridement and decortication. In particular, the soft tissue, such as fat and muscle, covering the vertebrae may be removed in order to allow the physician to visually identify the various "landmarks," or vertebral structures, which enable the physician to locate the location for attaching a fastener, such a fastener 600, discussed below, or other procedures, as will be described herein. Allowing visual identification of the

vertebral structures enables the physician to perform the procedure while viewing the surgical area through the endoscope, microscope, loupes, etc., or in a conventional, open manner.

[0105] Tissue debridement and decortication of bone are completed using one or more debrider blades, bipolar sheath, high speed burr, and additional conventional manual instruments. The debrider blades are used to excise, remove and aspirate the soft tissue. The bipolar sheath is used to achieve hemostasis through spot and bulk tissue coagulation. The debrider blades and bipolar sheath are described in greater detail in U.S. Patent No. 6,193,715, assigned to Medical Scientific, Inc., which is incorporated by reference in its entirety herein. The high speed burr and conventional manual instruments are also used to continue to expose the structure of the vertebrae.

[0106] A subsequent stage is the attachment of fasteners to the vertebrae V. Prior to attachment of the fasteners, the location of the fastener attachment is confirmed. In the exemplary embodiment, the pedicle entry point of the L5 vertebrae is located using visual landmarks as well as lateral and A/P fluoroscopy, as is known in the art. With continued reference to **FIGURE 25**, the entry point 92 is prepared with an awl 550. The pedicle hole 92 is completed using instruments known in the art such as a straight bone probe, a tap, and a sounder. The sounder, as is known in the art, determines whether the hole that is made is surrounded by bone on all sides, and that there has been no perforation of the pedicle wall.

[0107] After hole in the pedicle is provided at the entry point 92 (or at any point during the procedure), an optional step is to adjust the location of the distal portion of the expandable conduit 20. This may be performed by inserting the expander apparatus 200 into the expandable conduit 20, expanding the distal portions 210, and contacting the inner wall of the skirt portion 24 to move the skirt portion 24 to the desired location. This step may be performed while the endoscope 500 is positioned within the expandable conduit 20, and without substantially disturbing the location of the proximal portion of the expandable conduit 20 to which the endoscope mount platform 300 may be attached.

[0108] **FIGURES 26-27** illustrate a fastener 600 that is particularly applicable in a procedures involving fixation. The fastener 600 is described in greater detail in U.S. Patent application No. 10/075,668, filed February 13, 2002 and application No. 10/087,489, filed March 1, 2002, which are incorporated by reference in their entirety herein. Fastener 600

includes a screw portion 602, a housing 604, a spacer member 606, a biasing member 608, and a clamping member, such as a cap screw 610. The screw portion 602 has a distal threaded portion 612 and a proximal, substantially spherical joint portion 614. The threaded portion 612 is inserted into the hole 92 in the vertebrae, as will be described below. The substantially spherical joint portion 614 is received in a substantially annular, part spherical recess 616 in the housing 604 in a ball and socket joint relationship (see also **FIGURE 29**).

[0109] As illustrated in **FIGURE 27**, the fastener 600 is assembled by inserting the screw portion 602 into a bore in a passage 618 in the housing 604, until the joint portion 614 engages the annular recess 616. The screw portion 602 is retained in the housing 604 by the spacer member 606 and biasing member 608. The biasing member 608 provides a biasing force to drive the spacer member 606 in frictional engagement with the joint portion 614 of the screw member 602 and the annular recess 616 of the housing 604. The biasing provided by the biasing member 602 frictionally maintains the relative positions of the housing 604 with respect to the screw portion 602. The biasing member 608 is selected such that biasing force prevents unrestricted movement of the housing 604 relative to the screw portion 602. However, the biasing force is insufficient to resist the application of force by a physician to move the housing 604 relative to the screw portion 602. In other words, this biasing force is strong enough maintain the housing 604 stationary relative to the screw portion 602, but this force may be overcome by the physician to reorient the housing 604 with respect to the screw member 602, as will be described below.

[0110] In the illustrated embodiment, the biasing member 608 is a resilient ring having a gap 620, which permits the biasing member 608 to radially contract and expand. **FIGURE 27(a)** illustrates that the biasing member 608 may have an arched shape, when viewed end-on. The arched shape of the spring member 608 provides the biasing force, as will be described below. The spacer member 606 and the biasing member 608 are inserted into the housing 604 by radially compressing the biasing member into an annular groove 622 in the spacer member 606. The spacer member 606 and the biasing member 608 are slid into the passage 618 until the distal surface of the spacer member 606 engages the joint portion 614 of the screw portion 602, and the biasing member 608 expands radially into the annular groove 622 in the housing 604. The annular groove 622 in the housing 604 has a dimension

623 which is smaller than the uncompressed height of the arched shape of the biasing member 608. When the biasing member 608 is inserted in the annular groove 620, the biasing member 608 is flattened against its normal bias, thereby exerting the biasing force to the spacer member 606. It is understood that similar biasing members, such as coiled springs, belleville washers, or the like may be used to supply the biasing force described herein.

[0111] The spacer member 606 is provided with a longitudinal bore 626, which provides access to a hexagonal recess 628 in the proximal end of the joint portion 614 of the screw member 602. The proximal portion of the housing 604 includes a pair of upright members 630 and 631 that are separated by substantially "U"-shaped grooves 632. A recess for receiving elongated member 650 is defined by the pair of grooves 632 between upright member 630 and 631. Elongated member 650 to be placed distally into the housing 604 in an orientation substantially transverse to the longitudinal axis of the housing 604, as will be described below. The inner walls of he upright members 630 and 631 are provided with threads 634 for attachment of the cap screw 610 by threads 613 therein.

[0112] The fastener 600 is inserted into the expandable conduit 20 and guided to the prepared hole 92 in the vertebrae as a further stage of the procedure. The fastener 600 must be simultaneously supported and rotated in order to be secured in hole 92. In the illustrated embodiment the fastener 600 is supported and attached to the bone by an endoscopic screwdriver apparatus 660, illustrated in **FIGURES 28-29**. The screwdriver 660 includes a proximal handle portion 662 (illustrated in dashed line), an elongated body portion 664, and a distal tool portion 666.

[0113] The distal tool portion 666, as illustrated in greater detail in **FIGURE 29** includes a substantially hexagonal outer periphery which is received in the substantially hexagonal recess 628 in the joint portion 614 of the screw member 602. A spring member at the distal tool portion 666 releasably engages the hexagonal recess 628 of the screw member 602 to support the fastener 600 during insertion and tightening. In the illustrated embodiment, a spring member 672 is configured to engage the side wall of the recess 628. More particularly, a channel/groove is provided in the tip portion 666 for receiving the spring member 672. The channel/groove includes a medial longitudinal notch portion 676, a

proximal, angled channel portion 678, and a distal substantially transverse channel portion 680. The spring member 672 is preferably manufactured from stainless steel and has a medial portion 682 that is partially received in the longitudinal notch portion 676, an angled proximal portion 684 which is fixedly received in the angled channel portion 678, and a transverse distal portion 686 which is slidably received in the transverse channel 680. The medial portion 682 of the spring member 672 is partially exposed from the distal tip portion 666 and normally biased in a transverse outward direction with respect to the longitudinal axis (indicated by arrow E), in order to supply bearing force against the wall of the recess 628. Alternatively the distal tip portion of the screw driver may be magnetized in order to hold the screw portion 602. Similarly, the distal tip portion may include a ball bearing or similar member which is normally biased in a radially outward direction to engage the interior wall of the recess 628 to secure the fastener 600 to the screwdriver distal tip 666.

[0114] The insertion of the fastener 600 into the prepared hole 92 may be achieved by insertion of screwdriver 660 into conduit 20 (indicated by arrow G). This procedure may be visualized by the use of the endoscope 500 in conjunction with fluoroscopy. The screw portion 602 is threaded into the prepared hole 92 by the endoscopic screwdriver 660 (indicated by arrow H). The endoscopic screwdriver 660 is subsequently separated from the fastener 600, by applying a force in the proximal direction, and thereby releasing the distal tip portion 666 from the hexagonal recess 628 (e.g., causing the transverse distal portion 686 of the spring member 672 to slide within the transverse recess 680 against the bias, indicated by arrow F), and removing the screwdriver 660 from the expandable conduit 20. An alternative method may use a guidewire, which is fixed in the hole 92, and a cannulated screw which has an internal lumen (as is known in the art) and is guided over the guidewire into the hole 92. The screwdriver would be cannulated as well to fit over the guidewire.

[0115] For a two-level fixation, it may be necessary to prepare several holes and attach several fasteners 600. Typically, the expandable conduit 20 will be sized in order to provide simultaneous access to all vertebrae in which the surgical procedure is being performed. In some cases, however, additional enlargement or repositioning of the distal portion of the expandable conduit may be required in order to have sufficient access to the

outer vertebrae, e.g., the L4 and S1 vertebrae. In the illustrated embodiment, the expander apparatus 200 may be repeatedly inserted into the expandable conduit 20 and expanded in order to further open or position the skirt portion 24. In one procedure, additional fasteners are inserted in the L4 and S1 vertebrae in a similar fashion as the fastener 600 inserted in to the L5 vertebra as described above. (When discussed individually or collectively, a fastener and/or its individual components will be referred to by the reference number, e.g., fastener 600, housing 604, and all fasteners 600. However, when several fasteners and/or their components are discussed in relation to one another, an alphabetic subscript will be used, e.g., fastener 600a is moved towards fastener 600b.)

[0116] In a further stage of the procedure, the housing portions 604 of the fasteners 600 are substantially aligned such that their upright portions 630 and 631 face upward, and the notches 632 are substantially aligned to receive the elongated member 650 therein. The frictional mounting of the housing 604 to the screw member 602, described above, allows the housing 604 to be temporarily positioned until a subsequent tightening step, described below. Positioning of the housing portions 604 may be performed by the use of an elongated surgical instrument capable of contacting and moving the housing portion to the desired orientation. One such instrument for positioning the housings 604 is a grasper apparatus 700, illustrated in **FIGURE 30**. The grasper apparatus 700 includes a proximal handle portion 702, an elongated body portion 704, and distal nose portion 706. The distal nose portion 706 includes a pair of grasping jaws 708a and 708b, which are pivotable about pin 710 by actuation of the proximal handle portion 702. The grasping jaws 708a and 708b are illustrated in the closed position in **FIGURE 30**. As is known in the art, pivoting the movable handle 714 towards stationary handle 714 causes longitudinal movement of actuator 716, which in turn pivots the jaw 708b towards an open position (illustrated in dashed line). The biasing members 718 and 720 are provided to return the handles 712 and 714 to the open position and bias the jaws 708a and 708b to the closed position.

[0117] A subsequent stage in the process is the insertion of the elongated member 650 into the expandable conduit. The elongated member 650 is manufactured from a biocompatible material and must be sufficiently strong to maintain the positioning of the vertebrae, or other body structures. In the exemplary embodiment, the elongated members

650 are manufactured from Titanium 6/4 or titanium alloy. Alternatively, the elongated member 650 may be manufactured from stainless steel or other suitable material. The radii and length of the elongated members 650 are selected by the physician to provide the best fit for the positioning of the screw heads. Such selection may be performed by placing the elongated member 650 on the skin of the patient overlying the location of the fasteners and viewed fluoroscopically. For example, a 70 mm preformed rod having a 3.5" bend radius may be selected for the spinal fixation.

[0118] The elongated member 650 is subsequently fixed to each of the fasteners 600, and more particularly, to the housings 604 of each fastener 600. The grasper apparatus 700, described above, is also particularly useful for inserting the elongated member 650 into the expandable conduit 20 and positioning it with respect to each housing 604. As illustrated in **FIGURE 30**, the jaws 708a and 708b of the grasper apparatus 700 each has a curved contact portion 722a and 722b for contacting and holding the outer surface of the elongated member 650.

[0119] As illustrated in **FIGURE 31**, the grasper apparatus 700 may be used to insert the elongated member 650 into the operative space 90 defined at least partially by the skirt portion 24 of the expandable conduit 20. The cut-out portions 56 and 58 provided in the skirt portion 24 assist in the process of installing the elongated member 650 with respect to the housings 604. The cut-out portions 56 and 58 allow an end portion 652 of the elongated member 650 to extend beyond the operative space without raising or repositioning the skirt portion 24. The elongated member 650 is positioned within the recesses in each housing 604 defined by grooves 632 disposed between upright members 630 and 631. The elongated member 650 is positioned in an orientation substantially transverse to the longitudinal axis of each housing 604.

[0120] Further positioning of the elongated member 650 may be performed by guide apparatus 800, illustrated in **FIGURE 32**. Guide apparatus 800 is useful in cooperation with an endoscopic screwdriver, such as endoscopic screwdriver 660 (illustrated in **FIGURE 28**), in order to position the elongated member 650, and to introduce and tighten the cap screw 610, described above and illustrated in **FIGURE 27**. Tightening of the cap screw 610 with respect to the housing 604 fixes the orientation of the housing 604 with

respect to the screw portion 602 and fixes the position of the elongated member 650 with respect to the housing 604.

[0121] In the illustrated embodiment, the guide apparatus 800 has a proximal handle portion 802, an elongated body portion 804, and a distal tool portion 806. The elongated body portion 804 defines a central bore 808 (illustrated in dashed line) along its longitudinal axis 810. The central bore 808 is sized and configured to receive the endoscopic screwdriver 660 and cap screw 610 therethrough. In the exemplary embodiment, the diameter of the central bore 808 of the elongated body portion 804 is about 0.384 - 0.388 inches in diameter, and the external diameter of the endoscopic screwdriver 660 (**FIGURE 28**) is about 0.25 inches. The proximal handle portion 802 extends transverse to the longitudinal axis 810, which allows the physician to adjust the guide apparatus 800 without interfering with the operation of the screwdriver 660.

[0122] The distal portion 806 of the apparatus includes several semicircular cut out portions 814 which assist in positioning the elongated member 650. As illustrated in **FIGURE 33**, the cut out portions 814 are sized and configured to engage the surface of elongated member 650 and move the elongated member 650 from an initial location (illustrated in dashed line) to a desired location.

[0123] As illustrated in **FIGURE 34**, the guide apparatus 800 is used in cooperation with the endoscopic screwdriver 660 to attach the cap screw 610. The distal end of the body portion 804 includes a pair of elongated openings 816, which permit the physician to endoscopically view the cap screw 610 retained at the distal tip 666 of the endoscopic screw driver 660.

[0124] The guide apparatus 800 and the endoscopic screwdriver 660 may cooperate as follows. The guide apparatus 800 is configured to be positioned in a surrounding configuration with the screwdriver 600. In the illustrated embodiment, the body portion 804 is configured for coaxial placement about the screwdriver 660 in order to distribute the contact force of the guide apparatus 800 on the elongated member 650. The distal portion 806 of the guide apparatus 800 may bear down on the elongated member 650 to seat the elongated member 650 in the notches 632 in the housing 604. The "distributed" force of the guide apparatus 800 may contact the elongated member 650 on at least one or

more locations. In addition, the diameter of central bore 808 is selected to be marginally larger than the exterior diameter of cap screw 610, such that the cap screw 610 may freely slide down the central bore 808, while maintaining the orientation shown in **FIGURE 34**. This configuration allows the physician to have effective control of the placement of the cap screw 610 into the housing 604. The cap screw 610 is releasably attached to the endoscopic screwdriver 660 by means of spring member 672 engaged to the interior wall of hexagonal recess 611 as it is inserted within the bore 808 of the body portion 804 of guide apparatus 800. The cap screw 610 is attached to the housing 604 by engaging the threads 615 of the cap screw 610 with the threads 634 of the housing.

[0125] As illustrated in **FIGURE 35**, tightening of the cap screw 610 fixes the assembly of the housing 604 with respect to the elongated member 650. In particular, the distal surface of the cap screw 610 provides a distal force against the elongated member 650, which in turn drives the spacer member 606 against the joint portion 614 of the screw portion 602, which is consequently fixed with respect to the housing 604.

[0126] If locations of the vertebrae are considered acceptable by the physician, then the fixation procedure is substantially complete once the cap screws 610 have been attached to the respective housings 604, and tightened to provide a fixed structure as between the elongated member 650 and the various fasteners 600. However, if compression or distraction of the vertebrae with respect to one another is required additional apparatus would be used to shift the vertebrae prior to final tightening all of the cap screws 610.

[0127] In the illustrated embodiment, this step is performed with a surgical instrument, such as compressor-distractor instrument 900, illustrated in **FIGURE 36**, which is useful to relatively position bone structures in the cephcaudal direction and to fix their position with respect to one another. Thus, the compressor-distractor instrument 900 has the capability to engage two fasteners 600 and to space them apart while simultaneously tightening one of the fasteners to fix the spacing between the two vertebrae, or other bone structures. Moreover, the compressor-distractor instrument 900 may also be used to move two fasteners 600, and the vertebrae attached thereto into closer approximation and fix the spacing therebetween.

[0128] The distal tool portion 902 of the compressor-distractor instrument 900 is illustrated in **FIGURE 36**. (Further details of the compressor-distractor apparatus is described in co-pending U.S. application No. 10/178,875, filed June 24, 2002, entitled "Surgical Instrument for Moving Vertebrae," which is incorporated by reference in its entirety herein.) The distal tool portion 902 includes a driver portion 904 and a spacing member 906. The driver portion 904 has a distal end portion 908 with a plurality of wrenching flats configured to engage the recess 611 in the proximal face of the cap screw 610, and to apply torque to the cap screw. The driver portion 904 is rotatable about the longitudinal axis (indicated by arrow M) to rotate the cap screw 610 relative to the fastener 600. Accordingly, the driver portion 904 can be rotated to loosen the cap screw 610 on the fastener 600 and permit movement of the elongated member 650 connected with the vertebra relative to the fastener 600 connected with the vertebra. The cap screw 610 can also be rotated in order to tighten the cap screw 610 and clamp the elongated member 650 to the fastener 600.

[0129] The distal tool portion 902 may also include a spacing member, such as spacing member 906, which engages an adjacent fastener 600b while driver member 904 is engaged with the housing 604a to move the fastener 600b with respect to the fastener 600a. In the exemplary embodiment, spacing member 906 is a jaw portion which is pivotably mounted to move between a first position adjacent the driver portion and a second position spaced from the driver portion, as shown in **FIGURE 36**. The distal tip 910 of the spacing member 906 is movable relative to the driver portion 904 in a direction extending transverse to the longitudinal axis.

[0130] As illustrated in **FIGURE 36**, the spacer member 906 can be opened with respect to the driver portion 904 to space the vertebrae further apart (as indicated by arrow N). The distal portion 910 of the spacer member 906 engages the housing 604b of fastener 600b and moves fastener 600b further apart from fastener 600a to distract the vertebrae. Where the vertebrae are to be moved closer together, e.g. compressed, the spacer member 906 is closed with respect to the driver portion 904 (arrow P), as illustrated in **FIGURE 37**. The distal portion 610 of spacer member 606 engages housing 604b of fastener 600b and moves fastener 600b towards fastener 600a. When the spacing of the vertebrae is acceptable to the physician, the cap screw 610a is tightened by the driver member 904, thereby fixing the

relationship of the housing 604a with respect to elongated member 650, and thereby fixing the position of the vertebrae, or other bone structures, with respect to one another.

[0131] Once the elongated member 650 is fixed with respect to the fasteners 600, the procedure is substantially complete. The surgical instrumentation, such as the endoscope 500 is withdrawn from the surgical site. The expandable conduit 20 is also withdrawn from the site. The muscle and fascia typically close as the expandable conduit 20 is withdrawn through the dilated tissues in the reduced profile configuration. The fascia and skin incisions are closed in the typical manner, with sutures, etc. The procedure described above may be repeated for the other lateral side of the same vertebrae, if indicated.

II. MOTION PRESERVING STABILIZATION SYSTEMS

[0132] Another type of procedure that can be performed by way of the systems and apparatuses described hereinabove provides stabilization of skeletal portions, e.g. adjacent vertebrae in the spine, as would be the case in more conventional fixation procedures, but advantageously preserves a degree of normal motion. A variety of system and methods that may be used to provide motion preserving stabilization, such as dynamic stabilization, are described below. The access devices and systems described above enable these systems and methods to be practiced minimally invasively.

A. Stabilization Devices Allowing Axial Motion

[0133] A first type of motion preserving stabilization device is shown in **FIGURES 38-40**. In the illustrated embodiment, the motion preserving stabilization device 1000 is attached on the posterior side of the spine. However, the device 1000 may be modified for use on the anterior or lateral sides of the spine, or at locations between the anterior and lateral sides, or at locations between the lateral and posterior sides, e.g., at a posterolateral location. In one embodiment, the components of this stabilization device 1000 may be fabricated from a biocompatible metal, preferably titanium or a titanium alloy. The components may also be fabricated from other metals, or other suitable materials.

[0134] In one embodiment, the stabilization device 1000 comprises a plate 1004, a plurality of fasteners 1008, a plurality of fastener clamp portions 1012 and 1016, fastener spacers 1020, and stop locks 1024, as shown in **FIGURES 38-40**. The stabilization device 1000 and its components are further described in the following paragraphs.

[0135] In one embodiment, the plate 1004 is the framework upon which the other components are attached. In one embodiment, the plate 1004 is an elongate member having a caudal end and a cephalad end, and defining a longitudinal axis extending from the caudal end to the cephalad end. The plate 1004 may have a slot parallel to its longitudinal axis to receive and contain the fasteners 1008. The slot advantageously allows the fasteners 1008 to be infinitely positioned axially to place it into the desired position relative to the vertebra. The plate optionally may be formed from a single piece of metal. Another approach would be to provide preformed holes, which would limit the location of the fasteners 1008 with respect to the plate 1004. The plate 1004 may be curved or otherwise shaped or configured to allow for stabilizing a spine or positioning individual vertebrae as required. Although not shown, the plate 1004 may have one or more open ends. The open ends can enable different fastener elements to be more easily inserted, and may then be closed and stiffened with one or more stop locks 1024. In another embodiment, the slot need not extend the entire length of the plate 1004, but can provide a more limited range of potential axial positions. In another embodiment, the plate 1004 may have a more rod-like shape with a hollowed out portion adapted to engage a portion of the fasteners 1008. In another embodiment, the plate 1004 may incorporate a hinge by which it is attached to at least one fastener 1008, such that the at least one fastener 1008 can move with respect to at least one other fastener 1008.

[0136] In **FIGURE 39**, a partial cross-sectional view of one embodiment of the fastener 1008 is shown. The fastener 1008 may comprise a bone screw, such as a conventional pedicle screw similar to the fastener 600 described above. The fastener has tapered screw threads 1028 at a bone end 1032, a head which will accept a tool near a midsection 1036, and a machine screw threaded stud 1040 at a clamp end. In other embodiments, in place of a bone screw, other fastener means, such as straight pins or tapered pins, bone hooks, or others, may be used to provide attachment with the bone. In one embodiment, the fastener may also have a screwdriver slot to adjust the screw height as shown in **FIGURE 40**.

[0137] In one embodiment, the fastener 1008 is attached to the plate 1004 via the fastener clamp portions 1012 and 1016, shown in **FIGURE 40** and more clearly in the detailed view shown in **FIGURE 40**. In one embodiment, a nut 1044 clamps the upper

fastener clamp portion 1012, through the plate 1004, to the lower fastener clamp portion 1016, and against a collar 1048 on the fastener 1008 to give metal-to-metal clamping. Because of the metal-to-metal clamping, the fastener 1008 does not require anti-rotational locks such as auxiliary screw clamps, cams, wedges or locking caps. The metal-to-metal clamping of the fastener 1008 to the plate 1004 provides a fully rigid bone stabilizer system. In other embodiments, other means of attaching the plate 1004 to the fasteners 1008 may be used. The fastener clamp portions 1012 and 1016 may be machined to angular shapes to allow the fastener 1008 to be attached to the plate 1004 at different angles.

[0138] In one application, spacers 1020 are selectively installed between the fastener clamp portions 1012 and 1016 to allow axial motion of the fasteners 1008 along the slot with respect to the plate 1004. This spacer 1020 installation may preserve motion between the fasteners 1008 and the plate 1004. A spacer 1020 is a piece of material with a width greater than the width of the plate 1004 placed between the fastener clamp portions 1012 and 1016, such that the fastener clamp portions 1012 and 1016 fixedly contact the spacer 1020 and not the plate 1004. In one embodiment, because of the metal-to-metal clamping through the spacer 1020, auxiliary screw clamps such as a cam, a wedge or a locking cap may not be needed. To reduce the number of small parts, the lower fastener clamp portion 1016 and the spacer 1020 may optionally be fabricated as one integral part. If desired, in a rigid installation without a spacer 1020, the nut 1044 may force the fastener clamp portions 1012 and 1016 directly against the plate 1004.

[0139] In one embodiment, the stop locks 1024 may be clamped to the plate 1004 to maintain plate rigidity, and they may serve as travel limit stops to preserve or to favor motion in one direction and to limit or eliminate it in the opposite direction. This action is sometimes referred to herein as unidirectional, dynamized action of the fasteners 1008 with respect to the plate 1004. In one embodiment, the motion of the fasteners 1008 in a cephcaudal direction is limited. In one embodiment, the stop lock 1024 includes an upper portion, a lower portion, and a screw, which assembly can be attached to the plate 1004 in a similar manner to the fastener clamp portions 1012 and 1016 described above. The stop locks 1024 may be preloaded before tightening the stop lock screw. The stop locks 1024 may

also utilize springs or other force generating means to maintain compression on the vertebra/graft interface.

[0140] **FIGURE 38** shows that two stabilization devices 1000 can be used in conjunction on either side of the spinous processes, extending across three vertebrae. The stabilization device 1000 may alternatively be applied with one or more plates, and they may extend across two or more vertebrae.

[0141] In one embodiment, the unidirectional, dynamized action between the fasteners 1008 and plate 1004 preserves subsidence of the vertebrae, motion of an upper vertebra in a caudal direction. Among other advantages, this allows for graft resorption and settling. It also provides improved fusion conditions and prevents graft distraction. The stabilization device 1000 can also provide stress shielding to the stabilized vertebrae along other directions, including: rotation causing axial shear; lateral bending causing contralateral distraction; flexion causing posterior distraction; extension causing anterior distraction; horizontal force causing translation shear; and extension causing distraction.

[0142] Further details of structures that provide support and stability while preserving motion may be found in U.S. Patent Application No. 09/846,956 filed on May 1, 2001, published as U.S. Patent Application No. 2001/0037111 on November 1, 2001, which is hereby incorporated by reference in its entirety.

[0143] **FIGURE 41** shows another, similar embodiment of a motion preserving stabilization device 1100, which includes rods 1104, 1108 interconnected by a pair of plates 1112, 1116 each secured to a respective vertebra by multiple fasteners. In one embodiment, although the **FIGURE** shows an anterior insertion, the stabilization device 1100 is configured to be secured to the posterior side of the spine. The device 1100 may also be modified for use on the anterior or lateral sides of the spine, or at a location between the anterior and lateral sides, or at a location between the lateral and posterior sides, e.g., posterolateral.

[0144] In one embodiment, the stabilization device 1100 comprises a pair of surgically implantable rods 1104 and 1108. The stabilization device 1100 may also include first and second plates 1112 and 1116, which engage the rods 1104 and 1108; three fasteners 1120, 1124, and 1128 for connecting the first plate 1112 with the first vertebra V1; and three

fasteners 1132, 1136, and 1140 for connecting the second plate 1116 with the second vertebra V2.

[0145] The first rod 1104 is made of a suitable biocompatible material, such as titanium or stainless steel. In one embodiment, the first rod 1104 has an elongate cylindrical configuration and has a circular cross section taken in a plane extending perpendicular to the longitudinal central axis of the first rod. The first rod 1104 may also have a smooth outer surface. A first end portion of the first rod 1104 may comprise a cap 1144. The first rod 1104 may also have a second end portion 1148 opposite from the cap 1144. In one embodiment, the rod 1104 has a uniform diameter of about three (3) millimeters throughout its extent except at the cap 1144.

[0146] The second rod 1108 may be substantially identical to the first rod 1104. In one embodiment, the second rod 1108 has a first end portion comprising a cap 1152. The second rod 14 may also have a second end portion 1156 opposite from the cap 1152. In one embodiment, the rods 1104 and 1108 are bendable to a desired configuration to conform to a desired curvature of the spinal column. In a preferred embodiment, the rods 1104 and 1108 together have sufficient strength and rigidity to maintain the vertebrae V1 and V2 in a desired spatial relationship.

[0147] In one embodiment, the rods 1104 and 1108 have a length sufficient to enable them to span at least the two vertebrae V1 and V2. The length of the rods 1104 and 1108 will depend upon the condition to be corrected and the number of vertebrae to be held in a desired spatial relationship relative to each other by the stabilization device 1100. If more than two vertebrae are to be held in a desired spatial relationship relative to each other by the stabilization device 1100, the rods 1104 and 1108 could be longer, and more than two plates, such as the plates 1112 and 1116, may be used.

[0148] The first plate 1112 may be made of any suitable biocompatible material, such as titanium or stainless steel. In one embodiment, the first plate 1112 includes a main body portion. The main body portion of the first plate 1112 may have a planar outer side surface for facing away from the first vertebra V1. The first plate 1112 may have an arcuate inner side surface for facing toward the first vertebra V1. The inner side surface of the first

plate 1112 may engage the surface of the first vertebra V1 when the first plate is connected with the first vertebra as described below.

[0149] The main body portion of the first plate 1112 may also have a central portion which extends laterally between a first side portion 1160 and a second side portion 1164 of the first plate 1112. Because the inner side surface of the first plate 1112 has an arcuate configuration, the central portion of the first plate 1112 may be relatively thin as compared to the first side portion 1160 and to the second side portion 1164.

[0150] In one embodiment, the main body portion of the first plate 1112 also has first and second end portions 1168 and 1172. The first end portion 1168 of the first plate 1112 may include a planar first end surface of the first plate 1112. The second end portion 1172 may include a planar second end surface of the first plate 1112. The second end surface may extend parallel to the first end surface.

[0151] In one embodiment, a first rod passage is formed in the first side portion 1160 of the first plate 1112. The first rod passage is an opening that extends between the first and second end surfaces of the first plate 1112, in a direction parallel to the planar outer side surface of the first plate 1112. The first rod passage may be defined by a cylindrical surface and tapered pilot surfaces and at opposite ends of the cylindrical surface. The diameter of the cylindrical surface is optionally slightly greater than the diameter of the first rod 1104, so that the first rod 1104 and the first plate 1112 can be relatively movable.

[0152] In one embodiment, the second side portion 1164 of the first plate 1112 is a mirror image of the first side portion 1160. A second rod passage is formed in the second side portion 1164 of the first plate 1112. The second rod passage is an opening that extends between the first and second end surfaces of the first plate 1112, in a direction parallel to the planar outer side surface of the first plate 1112. The second rod passage extends parallel to the first rod passage. In one embodiment, the second rod passage is defined by a cylindrical surface and tapered pilot surfaces at opposite ends of the cylindrical surface. The diameter of the second rod passage is preferably the same as the diameter of the first rod passage. The diameter of the cylindrical surface is optionally slightly greater than the diameter of the second rod 1108, so that the second rod 1108 and the first plate 1112 can be relatively movable.

[0153] In one embodiment, a circular first fastener opening extends through the central portion of the first plate 1112. The first fastener opening has an axis that extends perpendicular to the plane of the outer side surface of the first plate 1112. The first fastener opening may be partially defined by a larger diameter cylindrical surface, which extends from the outer side surface of the first plate 1112 in a direction into the material of the central portion of the first plate 1112. The cylindrical surface is centered on the axis of the first fastener opening. The first fastener opening may also be partially defined by a smaller diameter cylindrical surface, which extends from the inner side surface of the first plate 1112 in a direction into the material of the central portion of the first plate to a location spaced radially inward from the larger diameter cylindrical surface. This smaller diameter cylindrical surface may also be centered on the axis of the first fastener opening 90.

[0154] In one embodiment, an annular shoulder surface extends radially (relative to the axis of the first fastener opening 90) between the larger and smaller diameter cylindrical surfaces. The shoulder surface and the larger diameter cylindrical surface define a recess in the outer side surface of the first plate 1112.

[0155] The main body portion of the first plate 1112 may also include a circular second fastener opening formed at a location adjacent to, but spaced apart from, the first rod passage in the first side portion 1160 of the first plate 1112. The second fastener opening may extend through both the second end surface of the first plate 1112 and the outer side surface of the first plate 1112. In one embodiment, the second fastener opening is partially defined by a larger diameter cylindrical surface, a smaller diameter cylindrical surface and an annular shoulder surface, in a configuration similar to that of the first fastener opening.

[0156] The main body portion of the first plate 1112 may also include a circular third fastener opening formed at a location adjacent to, but spaced apart from, the second rod passage in the second side portion 1164 of the first plate 1112. The third fastener opening may extend through both the second end surface of the first plate 1112 and the outer side surface of the first plate 1112. In one embodiment, the third fastener opening is partially defined by a larger diameter cylindrical surface, a smaller diameter cylindrical surface and an annular shoulder surface, in a configuration similar to that of the first fastener opening.

[0157] The second plate 1116 may be generally similar in configuration to the first plate 1112, with rod passages disposed on both sides. The second plate 1116 may be configured, however, so that the head ends of the fasteners 1136, 1140 received in certain fastener openings in the second plate 1116 are engageable with the rods 1104 and 1108 disposed in rod passages in the second plate 1116. This engagement can block movement of the second plate 1116 relative to the rods 1104 and 1108, in a manner described below.

[0158] One or both of the fastener openings receiving the fasteners 1136 or 1140 may be partially defined by a larger diameter cylindrical surface which extends from the outer side surface of the second plate 1116 in a direction into the material of the first side portion of the second plate. This larger diameter cylindrical surface is centered on an axis of the fastener opening. The larger diameter cylindrical surface may also intersect the cylindrical surface that defines a rod passage in the second plate 1116. Thus, the fastener opening overlaps a portion of a rod passage.

[0159] In one embodiment, the fasteners 1120, 1124, 1128, 1132, 1136, and 1140, which connect the first plate 1112 with the first vertebra V1, and the second plate 1116 with the second vertebra V2, may be identical to each other. These fasteners 1120, 1124, 1128, 1132, 1136, 1140 may comprise bone screws, such as conventional pedicle screws similar to the fastener 600 described above. In other embodiments, in place of a bone screw, other fastener means, such as straight pins or tapered pins, bone hooks, or others, may be used to provide attachment with the bone.

[0160] When the second plate 1116 is connected with the second vertebra V2, the fasteners 1132, 1136 and 1140 secure the second plate and the second vertebra. The outer fasteners 1136 and 1140 may also serve to interlock the second plate 1116 with the rods 1104 and 1108, by moving into engagement with the rods 1104 and 1108, respectively, when each fastener is fully screwed into a respective vertebra. In one embodiment, the engagement between the fasteners 1136 and 1140 and the rods 1104 and 1108 blocks movement of the fasteners 1136 and 1140 relative to the rods. As a result, the fasteners 1136 and 1140 may also block movement of the second plate 1116 relative to the rods 1104 and 1108. Other means of blocking the movement of the second plate 1115 relative to the rods 1104 and 1108 are well known to those of skill in the art.

[0161] In one embodiment, the first plate 1112, in contrast, preserves motion relative to the rods 1104 and 1108, because the second and third fastener openings are spaced apart from the first plate's rod passages. In a preferred embodiment, the first plate 1112 is thus movable relative to the second plate 1116. In other embodiments, this motion preserving stabilization system 1100 may consist of two or more movable plates like 1112, with no fixed plates like 1116.

[0162] Accordingly, the first vertebra V1 may be movable vertically downward relative to the second vertebra V2. This relative movement allows for the maintaining of a load on bone graft placed between the vertebrae V1 and V2. If the first plate 1112 were not movable vertically downward relative to the second plate 1116, then the distance between the vertebrae V1 and V2 would be fixed. If bone graft were placed between the vertebrae V1 and V2 and the bone graft resorbed sufficiently, the bone graft could possibly shrink out of engagement with one or both of the vertebrae V1 and V2. Allowing relative movement of the plates 1112 and 1116 can help to maintain a load on bone graft placed between the vertebrae V1 and V2 and maintains the vertebrae in contact with the bone graft to facilitate bone growth.

[0163] The caps 1144 and 1152 on the rods 1104 and 1108, respectively, limit movement of the first vertebra V1 in a direction away from the second vertebra V2. This helps to maintain the vertebrae V1 and V2 in contact with the bone graft.

[0164] The stabilization device 1100 can also provide stress shielding to the stabilized vertebrae along other directions, including: rotation causing axial shear; lateral bending causing contralateral distraction; flexion causing posterior distraction; extension causing anterior distraction; horizontal force causing translation shear; and extension causing distraction.

[0165] Further details of structures that provide support and stability while preserving motion may be found in U.S. Patent No. 6,036,693 filed on November 30, 1998, which is hereby incorporated by reference in its entirety.

B. <u>Stabilization Device Having a Flexible Elongate Member</u>

[0166] **FIGURE 42** shows another embodiment of a motion preserving stabilization device 1200. While the **FIGURE** shows one stabilization device 1200, extending across five vertebrae. As discussed more fully below, multiple stabilization

devices 1200 may be applied to a spine in parallel, and may extend across more or fewer vertebrae. The stabilization device 1200 includes an elongate member 1204 secured to a plurality of fasteners 1208. In one embodiment, each fastener 1208 is engaged to a respective one of the vertebrae V1, V2, V3, V4, V5. A coupling member 1212 is engaged to each of the fasteners 1208 with the elongate member 1204 positioned between each fastener 1208 and its respective coupling member 1212.

[0167] It should be understood that the stabilization device 1200 may be utilized in all regions of the spine, including the cervical, thoracic, lumbar, lumbo-sacral and sacral regions of the spine. Additionally, although the stabilization device 1200 is shown in **FIGURE 42** as having application in a posterior region of the spine, it may alternatively be applied in other surgical approaches and combinations of surgical approaches to the spine such that one or more stabilization devices 1200 are attached to the anterior, antero-lateral, lateral, and/or postero-lateral portions of the spine.

[0168] In one embodiment, the stabilization device 1200 allows at least small degrees of spinal motion between the vertebrae to which it is attached, since the stabilization device 1200 includes an elongate member 1204 that is at least partially flexible between adjacent fasteners 1208. It should be understood that the stabilization device 1200 can be used in conjunction with fusion or non-fusion treatment of the spine. In one embodiment, the elongate member 1204 is a tether made from one or polymers, such as, for example, polyester or polyethylene; one or more superelastic metals or alloys, such as, for example, nitinol; or from resorbable synthetic materials, such as, for example suture material or polylactic acid. It is further contemplated that the elongate member 1204 may have elasticity such that when tensioned it will tend to return toward its pre-tensioned state. In other embodiments, the shape and size of the elongate member 1204 can be modified to adjust its elasticity and flexibility along different axes.

[0169] The fasteners 1208 and coupling members 1212 described herein may be employed with the shown stabilization device 1200. In addition, it is contemplated that the fasteners 1208 and coupling members 1212 described herein may be employed in isolation or in devices that include two or more coupling members 1212 and fasteners 1208. Examples of other devices include: one or more elongate members 1204 extending laterally across a

vertebral body; one or more elongate members 1204 extending in the anterior-posterior directions across a vertebral body; one or more elongate members 1204 wrapped around a vertebral body; and combinations thereof. Further examples include application of the fasteners 1208 and coupling members 1212 of the present invention with bony structures in regions other than the spinal column.

[0170] In one embodiment, a fastener 1208 may comprise a bone screw, such as a conventional pedicle screw similar to the fastener 600 described above. In other embodiments, in place of a bone screw, other fastener means, such as straight pins or tapered pins, bone hooks, or others, may be used to provide attachment with the bone. Similarly, a coupling member 1212 may comprise a cap screw similar to the cap screw 610 described above. In another embodiment, the coupling member 1212 comprises a threadable portion to threadably engage the fastener 1208, and a penetrating element to penetrate the elongate member 1204. In other embodiments, the coupling member 1212 may comprise another means of engaging a fastener 1208 and the elongate member 1204.

[0171] The motion preserving elongate member 1204 of this stabilization device 1200 enables adjacent vertebrae to move relative to each other depending on the elongate member's 1204 flexibility, while partially reproducing the restorative forces of a healthy spine. Moreover, the stabilization device 1200 may be stiffer along the direction of the longitudinal axis, reducing the compressive forces imposed upon the intervertebral regions, and providing support for the spine's load-bearing functions.

[0172] Further details of structures that provide support and stability while preserving motion may be found in U.S. Patent Application No. 10/013,053 filed on Oct. 30, 2001, published as U.S. Patent Publication No. 2003/0083657 on May 1, 2003, and U.S. Patent Application No. 09/960,770 filed on Sep. 21, 2001, published as U.S. Patent Publication No. 2002/0013586 on January 31, 2002, which are hereby incorporated by reference in their entirety.

C. Stabilization Device with a Jointed Link Rod

[0173] **FIGURE 43** illustrates a portion of another embodiment of a stabilization device 1250. In one embodiment, the stabilization device 1250 is configured to be secured to the posterior side of the spine. However, the device 1250 may be modified for use on the

anterior or lateral sides of the spine, or at a location between the anterior and lateral sides, or at a location between the lateral and posterior sides, e.g., posterolateral.

[0174] In the example shown in **FIGURE 43**, a set of fasteners connected to at least two vertebrae may be interconnected by a link rod 1254 comprising at least two rigid segments 1254A and 1254B, which are interconnected by means of a damper element 1258 interposed between their facing free ends, so as to oppose elastic resistance between the segments 1254A and 1254B with amplitude that may be controlled not only in axial compression and traction a, but also in angular bending b.

[0175] A single link rod 1254 may include a plurality of dampers 1258 disposed between the vertebrae. Also, the link rod 1254 may advantageously be cut to a selected length and curved to a selected radius.

[0176] As can be seen more clearly in **FIGURE 43**, the damper element 1258 may be made up of two elastically deformable members 1258A disposed around the free end of a pin 1254Ba extending from one of the segments 1254B constituting the rod 1254. The pin 1254Ba may be engaged inside a housing 1262a formed in a blind sleeve or cage 1262 made at the free end 1254Aa of the other link segment 1254A. In one embodiment, the damper element 1258 comprises a rigid piston 1266 formed on the pin 1254Ba to constitute a joint 1266 making multidirectional relative pivoting possible between the cage 1262 and the pin 1254Ba, at least about axes contained in a plane perpendicular to the longitudinal axis x-x' of the damper element 1258 when the pin 1254Ba and the cage 1262 are in alignment.

[0177] In one embodiment, the resulting joint 1266 is of the ball-and-socket type that also allows the cage 1262 to rotate relative to the pin 1254Ba about the axis x-x'. The joint 1266 may comprise a collar projecting radially from the pin 1254Ba and having an outside surface with a rounded profile that is designed to come into contact with the inside surface of the housing 1262a in the cage 1262. In the embodiment shown in **FIGURE 43**, the collar 1266 is an integral part of the pin 1254Ba, although in other examples, the collar 1266 may comprise a separate ring that is fixed on the pin 1254Ba.

[0178] The collar 1266 is disposed relative to the pin 1254Ba in such a manner as to receive thrust on both of its lateral faces from two sets of spring washers 1270 each in the form of a pair of facing frustoconical cups of identical diameter stacked on the pin 1254Ba.

The washers 1270 and the joint 1266 occupy at least part of the circular section housing 1262a, whose end wall constitutes a compression abutment for one of the elastically deformable members 1258A. It should be observed that the spring washers 1270, which are also known as "Belleville" washers, can be replaced by other spring-like elements, such as elastomer rings.

[0179] In one embodiment, the housing 1262a of the cage 1262 is closed by a first washer 1274 secured to the cage 1262 and having an inside face against which there bears a second washer 1278 secured to the pin 1254Ba. The deformable members 1258A may be placed freely on the pin 1254Ba between the second washer 1278 and the end wall of the housing 1262a. For example, the first washer 1274, which constitutes an axial abutment, can be implemented in the form of a threaded ring screwed into tapping made inside the housing from its outer end, thereby making it possible to adjust the extension position of the damper. It should be observed that the second washer 1278, which is secured to the pin 1254Ba, constitutes a bearing surface for an elastically deformable member 1258A. This second washer 1278 can serve as an abutment for the damper in axial traction. This second washer 1278 thus makes it possible to exert compression force on the deformable member without damaging it. In addition, according to an advantageous characteristic, the second washer 1278 can be made of a material that is identical to that constituting the elastically deformable member, so as to make it possible to control the friction which appears between the second washer 1278 and the elastically deformable member 1258A.

[0180] The elastically deformable members 1258A are maintained with axial clearance that makes it possible, when they deform elastically, to accommodate relative axial movements in compression and traction between the pin 1254Ba and the cage 1262. For example, it is possible to obtain axial compression or traction having a value of 0.8 mm. In addition, the elastically deformable members 1258A may be mounted to allow multidirectional relative pivoting between the pin 1254Ba and the cage 1262. The washers 1270 may therefore be mounted inside the housing 1262a with clearance relative to the inside wall of the housing.

[0181] In one embodiment, the damper element 1258 includes an angular abutment for limiting the multidirectional relative pivoting to a determined value having an

amplitude of about 4 degrees. Thus, as can be seen more clearly in **FIGURE 43**, the displacement b of the pin 1254Ba in the cage 1262 relative to its normal, aligned position is 2 degrees. In the embodiment shown, the angular abutment is provided by the housing 1262a against which the pin 1254Ba comes into abutment, which pin 1254Ba has a predetermined amount of radial clearance relative to the housing 1262a to enable relative pivoting to take place through the predetermined angle b. Thus, the pin 1254Ba presents radial clearance both between its collar 1266 and the housing 1262a, and between its free end and a blind recess 1262b extending the housing 1262a. Relative pivoting between the cage 1262 and the pin 1254Ba is thus limited by implementing two angular abutments defined by the co-operation firstly between the collar 1266 and the housing 1262a, and secondly between the free end of the pin 1254Ba and the blind recess 1262b. It should be observed that the two abutments constituted in this way are set up in opposition about the axis x-x'. This allows limited bending to be obtained between the cage and the pin in all directions of angular displacement.

[0182] This motion preserving link rod 1254 of this stabilization device 1250 enables adjacent vertebrae to move relative to each other depending on the flexibility of the incorporated joint 1266, while partially reproducing the restorative forces of a healthy spine. Moreover, the stabilization device 1250 may be stiffer along the direction of the longitudinal axis, reducing the compressive forces imposed upon the intervertebral regions, and providing support for the spine's load-bearing functions.

[0183] Further details of structures that provide support and stability while preserving motion may be found in U.S. Patent No. 6,241,730 filed on November 27, 1998, which is hereby incorporated by reference in its entirety.

D. Stabilization Device with a Spring Element

[0184] **FIGURE 44** illustrates another embodiment of a stabilization device 1300. In one embodiment, the stabilization device 1300 is configured to be secured to the posterior side of the spine. However, the device 1300 may be modified for use on the anterior or lateral sides of the spine, or at a location between the anterior and lateral sides, or at a location between the lateral and posterior sides, e.g., posterolateral.

[0185] In one embodiment, the body 1304 of the stabilization device 1300 comprises a leaf spring 1308 in the form of a closed loop and in one piece with fasteners 1312. The stabilization device 1300 is preferably made of titanium or titanium alloy,

although other biocompatible materials may be used. In one embodiment, the spring 1308 defines two leaf spring parts 1308a, 1308b extending parallel to each other in the alignment direction 1316. The generatrix 1320 extends from front to rear, and defines the moving straight line, whose path defines the planar leaf spring 1308 of the stabilization device 1300.

[0186] The two parts 1308a, 1308b of the spring may be symmetrical to each other with respect to a median plane passing through the axis 1316. Each spring part forms a plurality of successive U-shapes alternately oriented in opposite directions in a plane perpendicular to the generatrix 1320. In one embodiment, each part 1308a, 1308b has three of these U-shapes. The U-shapes nearest the fasteners 1312 have their base facing towards the outside of the stabilizing device 1300, and the middle U-shape of each part has its base facing towards the inside of the stabilizing device 1300. Each part 1308a, 1308b therefore forms an undulation or zig-zag. To be more precise, the general shape of this embodiment is that of an inverted M.

[0187] In one embodiment, each fastener 1312 comprises two jaws 1328, which are symmetrical to each other with respect to the median plane, generally flat in shape and have a generatrix parallel to the generatrix 1320. The two jaws 1328 face each other. Their facing faces have profiled teeth 1332. Each jaw has a passage 1336 for inserting a tool for maneuvering the jaw and whose axis is parallel to the generatrix 1320. The bases of the jaws 1328 extend at a distance from each other from one end of the spring 1308. The two jaws 1328 are mobile elastically relative to each other. At rest they diverge from their base.

[0188] To fit the stabilizing device 1300, the jaws 1328 of each fastener 1312 may be forced apart using tools inserted into the passages 1336. The stabilizing device 1300 may then be placed as shown in **FIGURE 44** so that each spinous process 1340 is between the respective jaws 1328. The jaws are then released so that they grip the processes and are anchored to them by their teeth 1332.

[0189] The leaf spring parts 1308a, 1308b may extend laterally beyond the spinous processes 1340. They can be configured to impart a low stiffness to them. A stabilizing device 1300 may optionally be fabricated by spark erosion from a mass of metal; this fabrication process being particularly simple because of the profile of the device 1300. In one embodiment, this stabilizing device 1300 has a relatively low stiffness for lateral

flexing of the body, i.e. flexing about an axis parallel to the generatrix 1320. It has a high stiffness for flexing of the body from front to rear, i.e. flexing about an axis perpendicular to the direction 1316 and to the generatrix 1320. In other embodiments, the shape of the spring 1308 can easily be modified to increase or reduce at least one of the stiffnesses referred to above, independently of the volume available between the processes 1340.

[0190] Although the spring element 1308 resists deformation proportionally to an effective spring constant, its structure also preserves some amount of motion between adjacent vertebrae. In one embodiment, the spring 1308 may be configured to allow some proportion of the axial forces to be imposed upon the intervertebral region, while providing restorative forces. This motion preserving device thereby facilitates healing and shields the spine from some postoperative stress.

[0191] Further details of structures that provide support and stability while preserving motion may be found in U.S. Patent No. 6,440,169 filed on January 27, 1999, which is hereby incorporated by reference in its entirety.

E. Stabilization Device Made From Flexible Material

[0192] **FIGURE 45** illustrates another embodiment of a stabilization device 1350. In one embodiment, the stabilization device 1350 is configured to be secured to the posterior side of the spine. However, the device 1350 may be modified for use on the anterior or lateral sides of the spine, or at a location between the anterior and lateral sides, or at a location between the lateral and posterior sides, e.g., posterolateral.

[0193] In this embodiment of a stabilization device 1350, flexible implants 1354 are anchored to the adjacent vertebrae V1, V2 and V3. The implants 1354 preferably have a low profile and are conformable to the spinal anatomy to minimize intrusion into the surrounding tissue and vasculature. The implants 1354 attach to vertebrae and prevent separation of the vertebrae while allowing normal extension and articulation of the spinal column segment. Portions of the implants 1354 and the fasteners 1358 attaching the implant 1354 to vertebrae can be at least partially or fully embedded within the vertebrae to minimize intrusion into the surrounding tissue and vasculature.

[0194] It is contemplated that the flexible implants 1354 of the stabilization device 1350 described herein can be made from resorbable material, nonresorbable material and combinations thereof. In one example, resorbable implants 1354 can be used with

interbody fusion devices since a permanent exterior stabilization may not be desired after fusion of the vertebrae. It is also contemplated that the fasteners 1358 used to attach the implants 1354 to the vertebrae can be made from resorbable material, nonresorbable material, and combinations thereof.

[0195] The implants 1354 can be flexible, tear resistant, and/or suturable. The flexible implant 1354 can also be fabricated from synthetic flexible materials in the form of fabrics, non-woven structures, two or three dimensional woven structures, braided structures, and chained structures. The implants 1354 can also be fabricated from natural/biological materials, such as autograft or allograft, taken from patellar bone-tendon-bone, hamstring tendons, quadriceps tendons, or Achilles tendons, for example. Growth factors or cells can be incorporated into the implants 1354 for bone ingrowth and bony attachment or for soft tissue ingrowth. Possible growth factors that can be incorporated include transforming growth factor β1, insulin-like growth factor 1, platelet-derived growth factor, fibroblast growth factor, bone morphogenetic protein, LIM mineralization protein (LMP), and combinations thereof.

[0196] Possible implant materials include synthetic resorbable materials such as polylactide, polyglycolide, tyrosine-derived polycarbonate, polyanhydride, polyorthoester, polyphosphazene, calcium phosphate, hydroxyapatite, bioactive glass and combinations thereof. Possible implant materials also include natural resorbable materials such as autograft, allograft, xenograft, soft tissues, connective tissues, demineralized bone matrix, and combinations thereof. Possible implant material further include nonresorbable materials such as polyethylene, polyester, polyvinyl alcohol, polyacrylonitrile, polyamide, polytetrafluorethylene, poly-paraphenylene terephthalamide, cellulose, shape-memory alloys, titanium, titanium alloys, stainless steel, and combinations thereof.

[0197] The stabilization device 1350 described herein includes fasteners 1358 to attach the implant 1354 to the vertebrae. It is contemplated that the fasteners 1358 can be, for example, interference screws or anchors, gull anchors, suture anchors, pin fasteners, bone screws with spiked washers, staples, buttons, or bone screws such as the fastener 600 described above. It is contemplated that the fasteners 1358 can be made from resorbable materials, nonresorbable materials, and combinations thereof. Possible synthetic resorbable

materials include polylactide, polyglycolide, tyrosine-derived polycarbonate, polyanhydride, polyorthoester, polyphosphazene, calcium phosphate, hydroxyapatite, bioactive glass, and combinations thereof. Possible natural resorbable materials include cortical bone, autograft, allograft, and xenograft. Possible nonresorbable materials include carbon-reinforced polymer composites, shape-memory alloys, titanium, titanium alloys, cobalt chrome alloys, stainless steel, and combinations thereof.

[0198] Referring now to **FIGURE 45**, the stabilization device 1350 includes a flexible implant 1354 that extends along the posterior faces of vertebrae V1, V2 and V3, and is attached to a first vertebra V1 and a second vertebra V3. The flexible implant 1354 may be configured to resist extension, flexion, and/or lateral bending loads created by motion of the spinal column depending on the location or locations of the spinal column segment on which the implant 1354 is positioned.

[0199] In one embodiment, the flexible implant 1354 has a first end 1354a and an opposite second end 1354b. Vertebra V1 includes a first opening on its posterior face and a first tunnel extending therefrom. Vertebra V3 has a second opening on its posterior face and a second tunnel extending therefrom. The ends 1354a and 1354b are inserted into respective ones of the first and second tunnels through these openings. An fastener 1358a is also inserted through the opening in V1, and into the tunnel of vertebra V1 to secure end 1354a to vertebra V1. Similarly, an fastener 1358b is inserted through the opening in V3, and into the tunnel of vertebra V3 to secure end 1354b to vertebra V3. Fasteners 1358a, 1358b are illustrated as threaded interference screws that are embedded into vertebral bodies V1 and V3 so that they do not protrude from the posterior faces of vertebrae V1 and V2. However, other fasteners and fastening techniques described herein could also be employed with implant 1354.

[0200] In one embodiment, the fasteners 1358a, 1358b can be oriented at an angle, alpha, with respect to the axial plane of the spinal column, in order to provide a smooth transition for implant 1354 as it enters the openings of the vertebrae V1 and V3. This reduces stress concentrations at the junction between the implant 1354 and the vertebrae. In one embodiment, angle, alpha, is about 45 degrees. Other embodiments contemplate angular

orientations that range from 0 degrees to about 80 degrees and from about 25 degrees to 65 degrees.

[0201] The ends of implant 1354 and other possible implants can be provided with pigtails or other extensions of reduced size for insertion through the openings and tunnels formed in the vertebrae. It is also contemplated that the ends of the implant can include eyelets, holes, loops or other configuration suitable for engagement with an anchor. In another embodiment, not shown in the **FIGURE**, the implant 1354 may comprise a broad swath of material through which the fasteners 1358 are threaded to provide attachment to the underlying vertebrae.

[0202] In **FIGURE 45**, two stabilization devices 1350 are shown extending across three vertebrae. It is further contemplated that more or fewer stabilization devices 1350 may be applied to a spine in parallel, and may extend across more or fewer vertebrae.

[0203] While the implants 1354 do not provide stress shielding against compressive loading, they do provide stabilization by resisting extension, lateral bending, and rotation. Thus, this stabilization device provides some stabilization while preserving motion between the vertebrae. Further details of structures that provide support and stability while preserving motion may be found in U.S. Patent Application No. 10/078,522 filed on Feb. 19, 2002, published as U.S. Patent Publication No. 2002/0120269 on August 29, 2002, and U.S. Patent Application No. 10/083,199 filed on Feb. 26, 2002, published as U.S. Patent Publication No. 2002/0120270 on August 29, 2002, which are hereby incorporated by reference in their entirety.

III. FURTHER METHODS OF APPLYING A STABILIZATION DEVICE

[0204] **FIGURES 46 - 49** illustrate further methods of applying various types of motion preserving stabilization devices through an access device. The term "access device" is used in its ordinary sense (i.e. a device that can provide access) and is a broad term and it includes structures having an elongated dimension and defining a passage, e.g., a cannula or a conduit. These and similar methods also can be used to deliver any suitable stabilization device, including those hereinbefore described. Also, some aspects of these methods may be similar to or combinable with the methods described above in connection with the application of single or multi-level fixation devices.

[0205] **FIGURE 46** shows that in one method, an access device 1504 is advanced through an incision 1508 in the skin and is further advanced to a surgical location adjacent the spine of the patient. The term "surgical location" is used in its ordinary sense (i.e. a location where a surgical procedure is performed) and is a broad term and it includes locations subject to or affected by a surgery. The term "spinal location" is used in its ordinary sense (i.e. a location associated with a spine) and is a broad term and it includes locations near a spine that are sites for surgical spinal procedures. The access device 1504 may be advanced generally posteriorly. The terms "posterior" and "posteriorly" are used in their ordinary sense (i.e., from or through the rear-facing side of the patient) and are broad terms and they include an approach along any line generally behind and between the two lateral sides of the patient. In the illustrated embodiment, the access device 1504 is advanced along a generally postero-lateral approach and is positioned above a portion of the spine. In one application, the access device 1504 is positioned above at least one pedicular area of at least one of two adjacent vertebrae. In another application, the access device 1504 may be positioned above one or more pedicular areas of more than two adjacent vertebrae.

[0206] The access device 1504 may be similar to those described above, e.g., the expandable conduit 20, except as set forth below. The access device 1504 preferably has an elongate body 1510 that extends between a proximal end 1512 and a distal end 1516. The elongate body 1510 has a length between the proximal end 1512 and the distal end 1516 that is selected such that when the access device 1504 is applied to a patient during a surgical procedure, e.g., as shown in **FIGURES 46 - 49**, the distal end 1516 can be positioned inside the patient adjacent a spinal location. When so positioned, the selected length of the elongate body 1510 is such that the proximal end 1512 is located outside the patient at a suitable height.

[0207] In one embodiment, the elongate body 1510 comprises a proximal portion 1520 and a distal portion 1524. The proximal portion 1520 may have a generally oblong, oval, circular, or other suitable shape. The term "oblong" is used in its ordinary sense (i.e. having an elongated form) and is a broad term and it includes a structure having a dimension, especially one of two perpendicular dimensions, such as, for example, width or length, that is greater than another. The term "oval" is used in its ordinary sense (i.e., egg like or elliptical)

and is a broad term and includes oblong shapes having curved portions and oblong shapes having parallel sides and curved portions. The access device 1504 may further have a circular cross-section near the proximal end 1512, near the distal end 1516, at the proximal and distal ends 1512, 1516, and from the proximal end 1512 to the distal end 1516. As discussed above, in another embodiment, the access device 1504 has an oblong cross-sectional shape in the proximal portion 1520. In particular, the access device 1504 may have an oblong cross-section near the proximal end 1512, near the distal end 1516, at the proximal and distal ends 1512, 1516, and from the proximal end 1512 to the distal end 1516.

[0208] The access device 1504 preferably is capable of having a first configuration for insertion to the surgical location over the two vertebrae, which may be a relatively low-profile configuration, and a second configuration wherein increased access is provided to the surgical space. In the second configuration, the distal end 1516 may have a cross-sectional area that is larger than that of the first configuration at the distal end 1516. The distal portion 1524 of the access device 1504 may be expanded from the first configuration to the second configuration using an expander apparatus, such as the expander apparatus 200, as discussed above in connection with the skirt portion 24. When so expanded, the distal portion 1524, at the distal end 1516, defines a surgical space that includes a portion of at least one vertebra, and preferably two adjacent vertebrae.

[0209] The proximal and distal portions 1520, 1524 preferably are pivotally coupled to each other, as indicated by the arrows 1528 in **FIGURE 46**. The arrows 1528 indicate that the proximal portion 1520 may be pivoted medially and laterally with respect to the distal portion 1524. This pivotal motion tends to expose to a greater extent medial and lateral portions of the surgical space defined within the perimeter of the distal end 1516 of the access device 1504. In particular, pivoting the proximal portion 1520 laterally with respect to the distal portion 1524 exposes a portion of one or more vertebrae (or a portion of an external surface of an annulus A of an intervertebral disc) generally closer to the midline of the spine. Similarly, pivoting the proximal portion 1520 medially with respect to the distal portion 1524 exposes a portion of one or more vertebrae (or a portion of an external surface of the annulus A) generally closer to the transverse processes of the vertebrae.

[0210] In a like manner, as discussed further below, pivotal motion can be provided in the cephalad-caudal direction to expose generally cephalad or generally caudal peripheral portions of the surgical space defined within the perimeter of the distal end 1516.

[0211] At least one passage 1530 extends through the elongate body 1510 between the proximal end 1512 and the distal end 1516. The passage 1530 provides visualization of the surgical space in any suitable manner, e.g., by a viewing element, as discussed above. The passage 1530 also can provide sufficient access to the surgical space, e.g., adjacent the spine, such that components of a wide variety of dynamic stabilization systems, as well as implements adapted to deliver and apply such components, may be passed therethrough to the surgical location.

[0212] As discussed above, in the method illustrated by **FIGURE 46**, the distal end 1516 of the access device 1504 may be inserted postero-laterally, to a surgical location adjacent to at least one vertebra and preferably adjacent to the first vertebra V_1 and the second vertebra V_2 (See **FIGURE 47**). Insertion of the access device 1504 may be facilitated by first delivering a series of dilators, as discussed above in connection with the expandable conduit 20. In one application, as discussed above, after the access device 1504 has been delivered, it can be expanded to the second configuration, as indicated schematically in **FIGURE 46**. Further details of various additional embodiments of the access device 1504 may be found in U.S. Patent Application Serial No. 10/678,744, filed October 2, 2003, entitled MINIMALLY INVASIVE ACCESS DEVICE AND METHOD, which is hereby incorporated by reference herein in its entirety.

[0213] After the access device 1504 is delivered, a stabilization device 1540 is applied to the patient. In one embodiment, the stabilization device 1540 is configured to stabilize at least two adjacent vertebrae while preserving a degree of motion. The term "dynamic stabilization" is used in its ordinary sense (i.e., stabilizing adjacent vertebrae while permitting some degree of motion) and is a broad term and it includes stabilization that allows movement on a macroscopic or a microscopic level between adjacent vertebrae. The term "motion preserving" or "motion preservation" are used in their ordinary senses (i.e., maintaining the ability for motion or movement) and is a broad term and it includes restoring at least some motion that had been lost due to spinal conditions. In one embodiment, the

stabilization device 1540 includes a fastener, e.g., a bone anchor 1544, to be secured to each vertebrae V_1, V_2 and a connecting element 1548 configured to couple with the bone anchors 1544 and to extend between the adjacent vertebrae and to preserve motion of the adjacent vertebrae with respect to each other. The bone anchor 1544 may be a screw that is similar to a standard pedicle screw or may be similar to the fastener 600. In one embodiment, the bone anchor 1544 has an elongate body 1552 that extends between a proximal end 1556 and a distal end 1560. The distal end 1560 preferably is configured to engage bone, e.g., a vertebrae, in a suitable manner. In one embodiment, threads extend proximally from the distal end 1560. The proximal end 1556 of the bone anchor 1544 is configured to reside a suitable height above a vertebra when the bone anchor 1544 is applied thereto and to couple with the connecting element 1548 in a suitable manner, e.g., in a manner similar to the coupling between the elongated member 650 and the fastener 600.

[0214] The stabilization device 1540 is configured to allow movement, on a macroscopic or a microscopic level, between adjacent vertebrae to which it is applied. In one embodiment, the connecting element 1548 is configured such that motion is permitted at the point at which the connecting element 1548 is coupled with the bone anchor 1544 (See **FIGURE 38**). In another embodiment, the connecting element 1548 is configured such that movement is allowed at a location between two adjacent bone anchors 1544 applied to two adjacent vertebrae (See **FIGURE 42**).

[0215] In one application, the bone anchor 1544 is advanced through the proximal end 1512 of the access device 1504, through the passage 1530, and to the surgical location defined by the distal portion 1524 of the access device 1504. Thereafter, the bone anchor 1544 is advanced into a portion of a bone, e.g., into a pedicle of a vertebra which is to be dynamically stabilized.

[0216] Prior to insertion of the stabilization device 1540, surgical tools may be delivered through the access device 1504 to prepare the vertebrae V_1, V_2 to receive the bone anchors 1544. In various methods, bone probes, taps, or sounders may be inserted through the access device 1504 in order to perform procedures, e.g., drill and tap holes in the pedicle structures. Sounders may be used to assess the integrity of the portion of the vertebra or other bone where the bone anchor 1544 is to be applied. Bone probes may be used to make the

initial invasion into the bone. Taps may be used to thread a hole or to create a threaded hole in the bone into which a bone anchor 1544 may be advanced. Any other useful instruments or preparatory procedures known to those skilled in the art may also be used in various applications. These instruments preferably have lengths chosen such that when they are inserted through the access device 1504 to the surgical space, their proximal ends extend proximally of the proximal end 1512 of the access device 1504. This arrangement permits the surgeon to manipulate these instruments proximally of the access device 1504.

[0217] The bone anchor 1544 may be advanced by any suitable implant insertion tool, e.g., a bone anchor insertion tool 1580. In one embodiment, the bone anchor insertion tool 1580 is an elongate body 1584 that extends from a proximal end (not shown) configured to be grasped, e.g., manually by the surgeon, to a distal end 1588 and defines a length therebetween. The length of the elongate body 1584 is selected such that when the bone anchor insertion tool 1580 is inserted through the access device 1504 to the surgical space, the proximal end extends proximally of the proximal end 1512 of the access device 1504. This arrangement permits the surgeon to manipulate the bone anchor insertion tool 1580 proximally of the access device 1504.

[0218] The distal end 1588 is configured to engage the proximal end 1556 of the bone anchor 1544. For example, the distal end 1588 may have a cavity 1592 shaped to receive the proximal end 1556 of the bone anchor 1544. In one embodiment, the cavity 1592 engages the proximal end 1556 of the bone anchor 1544 in a manner to enable the bone anchor 1544 to be advanced, e.g., by transferring torsion applied to the proximal end of the bone anchor tool 1580 to the bone anchor 1544, into the pedicle or other bone segment. In another embodiment, the bone anchor insertion tool 1580 has a grip portion configured to engage the bone anchor 1544. In one embodiment, both the grip portion and the bone anchor 1544 are hexagonal and are configured such that the width of the proximal end of the bone anchor 1544 is slightly less than the width of the grip portion. Other means of coupling the bone anchor insertion tool 1580 to the bone anchor 1544 that permit the bone anchor 1544 to be inserted through the access device 1504 could also be used.

[0219] As discussed above, in one embodiment, the access device 1504 provides pivotal motion between the proximal and distal portions 1520, 1524, as indicated by the

arrows 1528. This pivotal motion enables the bone anchor 1544 to be applied within a range of angles with respect to the mid-plane of the spine. This enables the surgeon to select a preferred orientation of the bone anchor 1544 with respect to the vertebrae or other bone segment.

[0220] After the desired orientation of the bone anchor 1544 has been selected and the bone anchor 1544 has been advanced into the vertebra, as indicated in **FIGURE 46**, the bone anchor insertion tool 1580 may be disengaged from the proximal end 1566 of the bone anchor 1544 and withdrawn from the access device 1504, as indicated by the arrow 1596.

[0221] **FIGURE 47** shows that in one application, the access device 1504 is configured to extend between two adjacent vertebrae V_1, V_2 and to provide access to at least a portion of a pedicle of each of the vertebrae V_1, V_2 at the same time. In this manner, a first bone anchor 1544a may be applied to the first vertebra V_1 and a second bone anchor 1544b may be applied to the second vertebra V_2 (which may be superior or inferior to the first vertebra V_1) without the need to repeat the steps of inserting the access device 1504 over each vertebra to provide access to the pedicles thereof. Two separate access devices may be used to access the pedicles of adjacent vertebrae or one access device may be inserted twice, once over each of the adjacent vertebra. Further variations and combination are also possible, e.g., one or two access device may be applied on each side of the mid-line of the spine to access three adjacent vertebrae so that a multi-level dynamic stabilization device may be applied to couple three adjacent vertebrae. These procedures may be repeated on each side of the mid-line of the spine to apply multi-level dynamic stabilization devices on each side thereof.

[0222] An arrow 1594 in **FIGURE 47** indicates that the proximal portion 1520 may be pivoted with respect to the distal portion 1524 to provide access to the peripheral regions of the surgical space defined by the distal end 1512 of the access device 1504. This arrangement may simplify or facilitate the insertion of the bone anchors 1544a, 1544b.

[0223] Once the bone anchors 1544a, 1544b are applied to the patient, the connecting element 1548 may be advanced into the proximal end 1512 of the access device 1504, through the passage 1530, to the surgical location. Once at the surgical location, the

connecting element 1548 may be coupled with the bone anchors 1544a, 1544b in a suitable manner. As discussed above, one arrangement preserves motion of the vertebrae V_1, V_2 by permitting movement at or near the coupling of one or both of the connecting element 1548 and the bone anchors 1544. Another arrangement preserves motion of the vertebrae V_1, V_2 by permitting movement at a location between the bone anchors 1544a, 1544b. Another arrangement preserves motion of the vertebrae V_1, V_2 by permitting movement both at or near the connecting element / bone anchor coupling(s) and at a location between the bone anchors 1544a, 1544b.

[0224] In one embodiment, the connecting element 1548 is a flexible member that permits a degree of motion between the vertebrae V_1, V_2. **FIGURE 48** shows another embodiment of a connecting element 1598 that is a dynamic connecting element, e.g., an element that is configured such that movement is allowed at a location along the connecting element 1598 at a location between two adjacent bone anchors 1544 applied to two adjacent vertebrae (See **FIGURE 42**). In one embodiment, the connecting element 1598 has a first member 1600 coupled with the first bone anchor 1544a, and thereby with the first vertebra V_1, and a second member 1604 coupled with the second bone anchor 1544b, and thereby coupled with the second vertebra V_2. The first and second members 1600, 1604 may be rigid members or they may be flexible. The first member 1600 has a first end 1608 configured to couple with the first bone anchor 1544a and a second end with a chamber 1612 formed therein. The second member 1604 has a first end 1616 configured to couple with the second bone anchor 1544b and a second end with a piston 1620 arranged thereon. When the connecting element 1598 is assembled, the piston 1620 is arranged to move within the chamber 1612, providing motion indicated by an arrow 1624. The coupling of the piston 1620 and the chamber 1612 could also permit rotational motion of the first and second members 1600, 1604 as indicated by arrows 1628. The piston and chamber arrangement could be configured to permit a degree of pivoting of the first member 1600 with respect to the second member 1604, as indicated by an arrow 1632. Other arrangements of connecting elements could employ spring mechanisms, ball-and-socket joints, or any of the other geometries or arrangements described hereinabove.

[0225] The access device 1504 is advantageously configured to permit the foregoing steps to be performed in any order. For example, the connecting elements 1548, 1598 may be advanced to the surgical location before or after the first bone anchor 1544a is applied to the first vertebra V_1. In a like manner, the connecting elements 1548, 1598 may be advanced to the surgical location before the second bone anchor 1544b is applied to the second vertebra V_2. The connecting element 1548, 1598 may further be coupled with the first bone anchor 1544a before the second bone anchor 1544b is applied to the second vertebra V_2. Other orders of the foregoing steps are also possible.

[0226] In one procedure, once the bone anchors 1544 have been attached to the two adjacent vertebrae V_1, V_2, the connecting element 1548, 1598 may be delivered through the access device 1504 to couple with the bone anchors 1544. To facilitate insertion, a gripping apparatus, such as, e.g., the guide apparatus 800 described above, may be used to engage the connecting element 1548, 1598 and manipulate it through the access device 1504 to the surgical space. The connecting elements 1548, 1598 may take many forms depending on the particular stabilization device being delivered and the combination of vertebrae being treated.

[0227] In one embodiment, shown in **FIGURE 47**, the connecting element 1548 is a flexible member, such as that described above for stabilization device 1200. In another embodiment, shown in **FIGURE 48**, the connecting element 1598 may comprise a jointed link rod, such as that described above for stabilization device 1250.

[0228] Once the connecting element 1548, 1598 is appropriately seated on or near the bone anchors 1544, clamping elements may be inserted through the access device 1504 in a manner similar to that described above. The clamping elements may then be threadably or otherwise engaged with the bone anchors 1544, fixing the connecting element 1548, 1598 between the clamping element and the bone anchors 1544.

[0229] In some applications, a second access device, such as an expandable conduit 20 or other suitable access device, may be inserted into the patient. For example, a second access device could be inserted through a postero-lateral approach on the contralateral side of the spine, e.g., the opposite side of the spine across the mid-line of the spine, as indicated by an arrow 1636, to provide access to at least one of two or more adjacent

vertebrae. In another embodiment, a second access device may be inserted through an alternative approach on the same or opposite side of the spine to provide access to at least one of two or more adjacent vertebrae. This second access device may provide access to the vertebrae at about the same time as the first access device 1504 or during a later or earlier portion of a procedure. In one method, two stabilization devices are inserted from both sides of the spine using first and second access devices. Any combination of single, multiple stabilization devices, or stabilization device sub-components may be delivered through one or more access devices from any combination of one or more approaches, such as the approaches shown in **FIGURES 46-49**, or any other suitable approach.

[0230] **FIGURE 49** shows schematically another form of a dynamic stabilization treatment that could be provided through the access device 1504. In this treatment, one or more facet joints are removed and one or more artificial facet joints are inserted in their place. As above, the access device 1504 is delivered to the surgical location and is configured to provide access to a surgical location.

[0231] The facet joint may be removed using any suitable technique. Preferably, the facet joint is removed by inserting one or more implements to the surgical location through the access device 1504 and withdrawing facet joint fragments from the surgical location through the access device 1504.

[0232] After the facet joint is removed, a facet joint insertion tool 1660 may be advanced into the access device 1504 and may be advanced through the passage 1530 to a location adjacent where the natural facet joint had been.

[0233] The facet joint insertion tool 1660 preferably has an elongate body with a proximal end (not shown) that is configured to be manipulated by a surgeon and a distal end 1664 that is configured to selectively engage an artificial facet joint configured to preserve motion of the vertebrae forming the face joint. One such artificial face joint is the replacement facet joint 1668. Preferably the distal end 1664 includes a releasable clamp 1672 or other means for engaging the facet joint. In one embodiment, the clamp 1672 is releasable at the proximal end of the facet joint insertion tool.

[0234] The replacement facet joint 1668 preferably includes a generally superior member 1676, a generally inferior member 1680, and a connecting member 1684 that is

positioned between the superior member 1676 and the inferior member 1680. The superior member 1676 is configured to engage the generally superior aspect of the facet portion of the vertebra V_1. The inferior member 1680 is configured to engage the generally inferior aspect of the facet portion of the vertebra V_2. In one embodiment, bone growth features are provided on the surfaces of the superior and inferior members 1676, 1680 that are intended to engage the vertebral surfaces facing the facet joint. Although the bone growth features are shown as spikes in the illustrated embodiment, they may take any other suitable form. The connecting member 1684 is a deformable member in one embodiment that permits movement of the facets of the vertebrae V_1, V_2 with respect to each other to provide dynamic stabilization of the vertebrae V_1, V_2.

[0235] **FIGURE 49** illustrates at least two stages of a method for implanting replacement facet joint by way of the access device 1504 to provide dynamic stabilization. In one stage, when the replacement facet joint 1668 has been advanced to the surgical location, the facet joint insertion tool 1660 is caused to release the replacement facet joint 1668. This stage is represented by the schematic depiction of the replacement facet joint 1668 located between the distal end of the facet joint insertion tool 1660 and the vertebrae V_1, V_2. In another stage, the replacement facet joint 1668 is coupled with the adjacent vertebrae V_1, V_2 to form a replacement joint, as shown by the dashed outline of a replacement facet joint in positioned where the natural facet joint had been.

[0236] The proximal portion 1520 of the access device 1504 is pivotal with respect to the distal portion 1524 thereof, as illustrated by the dashed line representation of the proximal portion 1520 and the arrow 1594, as discussed above. This may facilitate one or more of the foregoing steps of facet joint replacement dynamic stabilization.

[0237] Although the forgoing procedures are described in connection with a single level postero-lateral procedure, other procedures are possible. For example, multiple level stabilization could be performed with the expandable conduit 20 or other suitable access device as described above with reference to **FIGURES 30-37**. As discussed above, other applications are also possible in which the access device 1504 is not expanded prior to delivery of the stabilization device 1500. In such applications, the access device 1504 remains in the first configuration while some, all, or any of the steps described above are

performed. Also, a motion preserving stabilization procedure could be combined with various spinal procedures used to partially fuse or rigidly fix adjacent vertebrae for stabilization along any suitable approach, e.g., anterior, lateral, posterior, transforaminal.

[0238] Although the methods discussed above are particularly directed to the insertion of a stabilization device, the access device 1504 may also be used advantageously to extract or remove the stabilization device. The surgical tools also may be further configured to facilitate removal as well as insertion. In one application, a motion preserving stabilization device may be replaced with a generally inflexible stabilization device, such as those described above, through the access device 1504. In another application, a previously inserted generally inflexible stabilization device may be replaced with a motion preserving stabilization device, such as those described above, through the access device 1504.

[0239] The foregoing methods and apparatuses advantageously provide minimally invasive treatment of a person's spine in a manner that preserves some degree of motion between the vertebrae. Accordingly, trauma to the patient may be reduced thereby, and recovery time shortened. As discussed above, the stabilization devices described herein provide a more normal post-recovery range of motion of the spine, which can reduce the need for additional procedures.

[0240] It will be understood that the foregoing is only illustrative of the principles of the invention, and that various modifications, alterations, and combinations can be made by those skilled in the art without departing from the scope and spirit of the invention.